HORIZON PHARMA PUBLIC LIMITED COMPANY

(Exact name of Registrant as specified in its charter)

Ireland
(State or other jurisdiction of incorporation or organization)

Connaught House, 1st Floor
1 Burlington Road, Dublin 4, Ireland
(Address of principal executive offices)

Not Applicable
(I.R.S. Employer Identification No.)

011 353 1 772 2100
(Registrant's telephone number, including area code)

Ordinary shares, nominal value $0.0001 per share
Name of Each Exchange on Which Registered

The NASDAQ Global Market

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ☑ Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the registrant’s voting ordinary shares held by non-affiliates of the registrant, based upon the $15.82 per share closing sale price of the registrant’s ordinary shares on June 30, 2014 (the last business day of the registrant’s most recently completed second quarter), was approximately $1.0 billion. Solely for purposes of this calculation, the registrant’s directors and executive officers and holders of 10% or more of the registrant’s outstanding ordinary shares have been assumed to be affiliates and an aggregate of 9,164,811 shares of the registrant’s voting ordinary shares held by such persons on June 30, 2014 are not included in this calculation.

As of February 20, 2015, the registrant had outstanding 125,100,210 ordinary shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive Proxy Statement for the registrant’s 2015 Annual Meeting of Shareholders are incorporated by reference into Part III of Annual Report on this Form 10-K.
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**FORM 10-K — ANNUAL REPORT**  
For the Fiscal Year Ended December 31, 2014  
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This Annual Report on Form 10-K contains “forward-looking statements” — that is, statements related to future, not past, events — as defined in Section 21E of the Securities Exchange Act of 1934, as amended, that reflect our current expectations regarding our future growth, results of operations, financial condition, cash flows, performance, business prospects, and opportunities, as well as assumptions made by, and information currently available to, our management. Forward-looking statements include any statement that does not directly relate to a current or historical fact. We have tried to identify forward-looking statements by using words such as “believe,” “may,” “could,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “seek,” “plan,” “expect,” “should,” or “would.” Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to successfully execute our sales and marketing strategy, including continuing to successfully recruit and retain sales and marketing personnel in the United States and to successfully build the market for our products in the United States; whether we will be able to realize the expected benefits of strategic transactions, such as our merger with Vidara Therapeutics International Public Limited Company and our acquisition of the U.S. rights to PENNSAID 2%, including whether and when such transactions will be accretive to our net income; the rate and degree of market acceptance of, and our ability and our distribution and marketing partners’ ability to obtain coverage and adequate reimbursement for, any approved products; our ability to maintain regulatory approvals for our products; our need for and ability to obtain additional financing; the accuracy of our estimates regarding expenses, future revenues and time to profitability; our ability to successfully execute our strategy to develop, acquire or in-license additional products or acquire companies; our ability to manage our anticipated future growth; the ability of our products to compete with generic products, especially those representing the active pharmaceutical ingredients in our products as well as new products that may be developed by our competitors; our ability and our distribution and marketing partners’ ability to comply with regulatory requirements regarding the sales, marketing and manufacturing of our products and product candidates; the performance of our third-party distribution partners, licensees and manufacturers over which we have limited control; our ability to obtain and maintain intellectual property protection for our products; our ability to defend our intellectual property rights with respect to our products; our ability to operate our business without infringing the intellectual property rights of others; the loss of key commercial or management personnel; regulatory developments in the United States and other countries; and other risks detailed below in Part I — Item 1A. “Risk Factors.”

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Item 1. Business

Merger with Vidara

On September 19, 2014, the businesses of Horizon Pharma, Inc., or HPI, and Vidara Therapeutics International Public Limited Company, or Vidara, were combined in a merger transaction, or the Merger, accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with HPI treated as the acquiring company in the Merger for accounting purposes. As part of the Merger, a wholly-owned subsidiary of Vidara merged with and into HPI, with HPI surviving the Merger as a wholly-owned subsidiary of Vidara and Vidara changed its name to Horizon Pharma plc, or New Horizon. Upon the consummation of the Merger, the historical financial statements of HPI became our historical financial statements. As a result of the Merger, we are organized under the laws of Ireland.

Unless otherwise indicated or the context otherwise requires, references to the “Company”, “New Horizon”, “we”, “us” and “our” refer to Horizon Pharma plc and its consolidated subsidiaries, including its predecessor,
Overview

We are a specialty biopharmaceutical company focused on improving patients’ lives by identifying, developing, acquiring or in-licensing and commercializing differentiated products that address unmet medical needs. We market a portfolio of products in arthritis, inflammation and orphan diseases. Our U.S. marketed products are ACTIMMUNE® (interferon gamma-1b), DUEXIS® (ibuprofen/famotidine), PENNSAID® (diclofenac sodium topical solution) 2% w/w, RAYOS® (prednisone) delayed-release tablets and VIMOVO® (naproxen/esomeprazole magnesium). We developed DUEXIS and RAYOS, acquired the U.S. rights to VIMOVO from AstraZeneca AB, or AstraZeneca, in November 2013, acquired the U.S. rights to ACTIMMUNE as a result of the Merger and acquired the U.S. rights to PENNSAID 2% from Nuvo Research Inc., or Nuvo, in October 2014. We market our products in the United States through our field sales force of approximately 375 representatives. Our strategy is to utilize the commercial strength and infrastructure we have established in creating a fully-integrated U.S.-focused specialty biopharmaceutical company to continue the successful commercialization of our existing product portfolio while also expanding and leveraging these capabilities further.

On April 23, 2011, the U.S. Food and Drug Administration, or FDA, approved DUEXIS, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis, or RA, osteoarthritis, or OA, and to decrease the risk of developing upper gastrointestinal, or GI, ulcers in patients who are taking ibuprofen for these indications. We began marketing DUEXIS to physicians in December 2011. In June 2012, we licensed DUEXIS rights in Latin America to Grünenthal S.A., a private company focused on the marketing of pain products.

Our second approved product in the United States, RAYOS, known as LODOTRA® outside the United States, is a proprietary delayed-release formulation of low-dose prednisone approved originally in Europe for the treatment of moderate to severe, active RA in adults, particularly when accompanied by morning stiffness. On July 26, 2012, the FDA approved RAYOS for the treatment of RA, polymyalgia rheumatica, or PMR, psoriatic arthritis, or PsA, ankylosing spondylitis, or AS, asthma and chronic obstructive pulmonary disease, or COPD, and a number of other conditions. We have been focusing our promotion of RAYOS in the United States on rheumatology indications, including RA and PMR, and currently are broadening the marketing efforts for RAYOS into multiple other indications. We began marketing RAYOS to a subset of U.S. rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of U.S. rheumatologists and key primary care physicians. LODOTRA is currently marketed outside the United States, excluding Japan and Canada, by our distribution partner, Mundipharma International Corporation Limited, or Mundipharma.

On November 18, 2013, we entered into agreements with AstraZeneca pursuant to which we acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with nonsteroidal anti-inflammatory drugs, or NSAIDs, in the United States. VIMOVO is a proprietary, fixed-dose, multi-layer, delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a proton pump inhibitor, or PPI, layer surrounding the core. VIMOVO was originally developed by Pozen Inc., or Pozen, together with AstraZeneca pursuant to an exclusive global collaboration and license agreement. On April 30, 2010, the FDA approved VIMOVO for the relief of the signs and symptoms of OA, RA and AS and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.
We announced the availability of Horizon-labeled VIMOVO on January 2, 2014, at which time we also began marketing VIMOVO with our primary care sales force.

On September 19, 2014, as a result of the Merger, we began marketing ACTIMMUNE, a bioengineered form of interferon gamma-1b, a protein that acts as a biologic response modifier. In the United States ACTIMMUNE is approved by the FDA for use in children and adults with chronic granulomatous disease, or CGD, and severe, malignant osteopetrosis, or SMO. ACTIMMUNE is indicated for reducing the frequency and severity of serious infections associated with CGD and for delaying time to disease progression in patients with SMO. We also plan to study ACTIMMUNE for potential additional indications, and the FDA has agreed to the primary endpoint for a Phase 3 study that will evaluate ACTIMMUNE in the treatment of Friedreich’s Ataxia, or FA. In February 2015, we submitted an IND application and anticipate the Phase 3 clinical study related to FA will begin enrolling patients in the second quarter of 2015.

On October 17, 2014, we acquired the U.S. rights to PENNSAID 2% from Nuvo for $45.0 million in cash. PENNSAID 2% is approved in the United States for the treatment of the pain of OA of the knee(s). As part of the acquisition, we entered into an exclusive eight-year supply agreement with Nuvo under which Nuvo will supply us product. We began marketing PENNSAID 2% in January 2015. In connection with our PENNSAID 2% acquisition, we expanded our primary care sales force by 75 additional representatives. Our primary care representatives are now marketing DUEXIS, PENNSAID 2% and VIMOVO.

Another key part of our commercial strategy is to encourage physicians to have their patients agree to fill prescriptions through our Prescriptions-Made-Easy, or PME, specialty pharmacy program, which enables uninsured or commercially insured patients’ enhanced access to our products by providing financial assistance to reduce eligible patients’ out of pocket costs for prescriptions filled via a PME-participating mail order pharmacy. Through PME, prescriptions for our products are filled by designated mail order specialty pharamacies, with the product shipped directly to the patient. Because the patient out of pocket cost for our products when dispensed through the PME program may be significantly lower than such costs when our products are dispensed outside of the PME program, prescriptions filled through our PME program are therefore less likely to be subject to the efforts of traditional pharmacies to switch a physician’s intended prescription of our products to a generic or over the counter brand. We expect that continued adoption of our PME program by physicians will be important to our ability to gain market share for our products as pressure from healthcare payors and PBMs, to use less expensive generic or over the counter brands instead of branded products increases. We believe the continued expansion of our PME program will allow us to largely mitigate the potential impact of our products being placed on the exclusion lists implemented by PBMs.

Our principal executive offices are located at Connaught House, 1 Floor, 1 Burlington Road, Dublin 4, Ireland and our telephone number is +011 353 1 772 2100. Our website address is www.horizonpharma.com. The information contained in or that can be accessed through our website is not part of this report.

“Horizon Pharma,” “Horizon Therapeutics,” a stylized letter “H,” “ACTIMMUNE,” “DUEXIS,” “LODOTRA,” “PENNSAID 2%,” “RAYOS,” and “VIMOVO” are registered trademarks in the United States and/or certain other countries. This report also includes references to trademarks and service marks of other entities and those trademarks and service marks are the property of their respective owners.

Our Strategy

Our strategy is to utilize the commercial strength and infrastructure we have established in creating a fully-integrated U.S.-focused specialty biopharmaceutical company to continue the successful commercialization of our existing product portfolio while also expanding and leveraging these capabilities by identifying, developing, acquiring or in-licensing and commercializing additional differentiated products that address unmet medical needs. We have entered into licensing or additional distribution arrangements for the commercialization of our products outside the United States, such as our relationship with Mundipharma for the commercialization
of LODOTRA outside of the United States, excluding Japan and Canada, and our relationship with Grünenthal for the commercialization of DUEXIS in Latin America.

**Our Products**

We believe that our products address unmet therapeutic needs in arthritis, pain, inflammatory and/or orphan diseases and provide significant advantages over existing therapies.

Our current product portfolio consists of the following:

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<th>Products</th>
<th>Disease</th>
<th>Phase of Development</th>
<th>Marketing Rights</th>
<th>Territory</th>
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<tr>
<td>ACTIMMUNE</td>
<td>CGD and SMO</td>
<td>FDA approved CGD on February 25, 1999 and SMO on February 10, 2000</td>
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<td>United States and selected foreign countries</td>
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<td>FA</td>
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<td>DUEXIS</td>
<td>Signs and symptoms of OA and RA</td>
<td>FDA approved on April 23, 2011; UK National Marketing Authorization approved on March 6, 2013</td>
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<td>Worldwide excluding Latin America</td>
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<tr>
<td>PENNSAID 2%</td>
<td>Pain of OA of the knee(s)</td>
<td>FDA approved January 16, 2014</td>
<td>Horizon Pharma</td>
<td>United States</td>
</tr>
<tr>
<td>RAYOS/LODOTRA</td>
<td>RA, multiple other indications</td>
<td>FDA approved July 26, 2012, approved and marketed in Europe and certain Asian and other countries</td>
<td>Horizon Pharma</td>
<td>Worldwide, excluding Europe, certain Asian, Latin American, Middle East, North African, and other countries</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mundipharma</td>
<td>Europe, certain Asian, Latin American, Middle East, North African, and other countries</td>
</tr>
</tbody>
</table>

| VIMOVO   | Signs and symptoms of OA, RA and AS | FDA approved April 30, 2010 | Horizon Pharma | United States |

**PAIN AND ARTHRITIS**

**Markets for Our Products**

Pain is a serious and costly public health concern. In 2010, the U.S. National Center for Health Statistics reported that approximately 30% of U.S. adults 18 years of age and over reported recent symptoms of pain, aching or swelling around a joint within the past 30 days.

Some of the most common and debilitating chronic inflammation and pain-related diseases are OA, RA and acute and chronic pain. According to National Health Interview Survey data analyzed by the U.S. Centers for Disease Control and Prevention, from 2010-2012, 52.5 million U.S. adults 18 years of age and over had reported being diagnosed with some form of arthritis. With the aging of the U.S. population, the prevalence of arthritis is...
expected to rise by approximately 40% by 2030, impacting 67 million people in the United States. People with these diseases may become increasingly debilitated as the disease progresses, experiencing not only significant pain but also loss of mobility, independence and the ability to work, thereby potentially placing a significant burden on family caregivers and healthcare and social services. In addition, patients suffering from chronic inflammatory diseases tend to have shortened life expectancies as a direct result of these diseases. According to the American Pain Foundation Fact Sheet and the U.S. Centers for Disease Control and Prevention:

- the annual cost of chronic pain in the United States, including healthcare expenses, lost income and lost productivity is estimated to be approximately $100 billion;
- arthritis and related conditions, such as OA, cost the U.S. economy nearly $128 billion per year in medical care and indirect expenses, including lost wages and productivity; and
- pain is the second leading cause of medically related work absenteeism, resulting in more than 50 million lost workdays each year.

In addition, the Arthritis Foundation reports 992,100 hospitalizations and 44 million office visits in the United States annually for arthritis alone.

**Osteoarthritis**

OA is a type of arthritis that is caused by the breakdown and eventual loss of the cartilage of one or more joints. Cartilage is a protein substance that serves as a cushion between the bones of the joints. OA is also known as degenerative arthritis. Among the over 100 different types of arthritis conditions, OA is the most common and occurs more frequently with age. Before age 45, OA occurs more frequently in males. After age 50, it occurs more frequently in females. OA commonly affects the hands, feet, spine and large weight-bearing joints, such as the hips and knees. Symptomatic knee arthritis is the most common form of arthritis in the United States. Over 9 million adults report symptomatic OA of the knee. NSAIDs are prescribed over 100 million times per year in the United States. Most cases of OA have no known cause and are referred to as primary OA.

Symptoms of OA manifest in patients as joint pain, tenderness, stiffness, limited joint movement, joint cracking or creaking (crepitation), locking of joints and local inflammation. OA can also lead to joint deformity in later stages of the disease. Many drugs are used to treat the inflammation and pain associated with OA, including aspirin and other NSAIDs, such as ibuprofen, naproxen and diclofenac, that have a rapid analgesic and anti-inflammatory response.

**Rheumatoid Arthritis**

RA is a chronic disease that causes pain, stiffness and swelling, primarily in the joints. According to a 2006 DataMonitor report, 2.9 million people in the United States suffer from RA, of which 1.8 million are diagnosed and treated with various drugs. RA has no known cause, but unlike OA, RA is not associated with factors such as aging. RA occurs when the body’s immune system malfunctions, attacking healthy tissue and causing inflammation, which leads to pain and swelling in the joints and may eventually cause permanent joint damage and painful disability. The primary symptoms of RA include progressive immobility and pain, especially in the morning, with long-term sufferers experiencing continual joint destruction for the remainder of their lives. There is no known cure for RA. Once the disease is diagnosed, treatment is prescribed for life to alleviate symptoms and/or to slow or stop disease progression.

RA treatments include medications, physical therapy, exercise, education and sometimes surgery. Early, aggressive treatment of RA can delay joint destruction. Treatment of RA usually includes multiple drug therapies taken concurrently. Disease-modifying anti-rheumatic drugs, or DMARDs, are the current standard of care for the treatment of RA, in addition to rest, exercise and anti-inflammatory drugs such as NSAIDs. Methotrexate is the most commonly prescribed DMARD for the treatment of RA. Other common agents for the treatment of RA
include corticosteroids and biologic agents. Over the last decade, the advent of biologic agents has transformed the treatment of RA. Tumor necrosis factor, or TNF, inhibitors are the primary biologic agents used today to treat RA. Although effective for treatment of RA, these agents are costly and, because they are very potent immunosuppressants, may increase the risk of infection. Corticosteroids, such as prednisone, effectively reduce joint swelling and inflammation and, in low doses, have been shown to enhance DMARD therapy and slow the progression of RA, but at high doses are associated with potential for significant long-term adverse side effects such as osteoporosis, cardiovascular disease and weight gain. An additional limitation of RA treatment with corticosteroids is related to the time at which patients’ pro-inflammatory cytokines are at peak levels. Increased levels of pro-inflammatory cytokines during the early morning hours are a known cause of morning stiffness and decreased mobility of RA. Interleukin 6, or IL-6, levels are substantially increased in patients with RA in general and show a significant circadian variation in these levels. Timing a dose of medicine to coincide with the rise of RA symptoms may be a good option for patients with RA.

Because RA has the potential to cause serious damage to joints and bones, physicians typically treat patients aggressively, including with combination therapies to reduce pain and inflammation and to slow the progression of the disease. Research sponsored by Mundipharma and conducted by Ipsos MORI involving 750 RA patients from 11 European countries found that 60% of surveyed patients with RA indicated that pain and morning stiffness control their lives. Additionally, 74% of people with pain and morning stiffness as a result of their RA indicated that they are either unemployed, retired early or are on sick leave as a result of RA and 58% say they are frustrated emotionally because they find it difficult to do everyday tasks due to morning stiffness caused by their RA.

Polymyalgia Rheumatica

PMR is an inflammatory disorder that causes significant muscle pain and stiffness. The pain and stiffness often occur in the shoulders, neck, upper arms and hip with pronounced morning stiffness lasting at least one hour. Symptoms of PMR usually begin within two weeks. Most people who develop PMR are older than 65 years of age. It rarely affects people younger than 50. There are approximately 1.1 million patients with PMR in the United States and it affects one in every 133 people over the age of 50. Prednisone is the standard of care for treating PMR and treatment is generally initiated at a relatively high dose (e.g., 10-20 mg per day) and reduced as clinical improvement is seen. Treatment usually lasts 18-24 months. Similar to RA, PMR is associated with circadian patterns of IL-6 elevation in early morning hours.

Ankylosing Spondylitis

AS is a type of arthritis that affects the spine. AS symptoms include pain and stiffness from the neck down to the lower back. The spine’s bones (vertebrae) may grow or fuse together, resulting in a rigid spine. These changes may be mild or severe, and may lead to a stooped-over posture. Early diagnosis and treatment helps control pain and stiffness and may reduce or prevent significant deformity.

Market Opportunity and Limitations of Existing Treatments

NSAIDs are very effective at providing pain relief, including pain associated with OA and RA; however, there are significant upper GI-associated adverse events that can result from the use of NSAIDs. As a result, COX-2 inhibitor drugs (i.e., Vioxx™, Merck & Co., Inc.; Celebrex and Bextra™, Pfizer Inc.) were introduced to the market in order to provide pain and arthritis relief with reduced risk of significant upper GI-associated adverse events. The COX-2 drugs generated approximately $6.3 billion in sales at their peak in 2004. However, safety concerns associated with COX-2 inhibitor drugs led to the withdrawal of Vioxx and Bextra from the market in 2004 and a significant decline in the use of Celebrex. In the United States alone, over $3 billion in sales of COX-2 inhibitor drugs were lost. As a result, demand for traditional prescription NSAIDs, such as ibuprofen and meloxicam, has increased dramatically.
According to a 2004 article published in Alimentary Pharmacology & Therapeutics, significant GI side effects, including serious ulcers, afflict up to approximately 25% of all chronic arthritis patients treated with NSAIDs for three months, and OA and RA patients are two to five times more likely than the general population to be hospitalized for NSAID-related GI complications. It is estimated that NSAID-induced GI toxicity causes over 16,500 related deaths in OA and RA patients alone and over 107,000 hospitalizations for serious GI complications each year. In more than 70% of patients with these serious GI complications, there are no prior symptoms.

Despite the fact that GI ulcers are one of the most prevalent adverse events resulting from the use of NSAIDs in the United States, according to a 2006 article published in BMC Musculoskeletal Disorders, eleven observational studies indicated that physicians do not commonly co-prescribe GI protective agents to high-risk patients. Physicians prescribe concomitant therapy to only 24% of NSAID users, and studies show sub-optimal patient compliance with concomitant prophylaxis therapy. According to a 2003 article published in Alimentary Pharmacology & Therapeutics, in a study of 784 patients, 37% of patients were non-compliant, a rate increasing to 61% in patients treated with three or more drugs. This noncompliance results in a substantial unmet clinical need, which we believe can be appropriately addressed with DUEXIS or VIMOVO, creating smarter solutions for both patients and physicians.
According to a 2006 DataMonitor report, there were approximately 4.9 million RA patients in the United States, Japan, France, Italy, Spain, Germany and the United Kingdom, or UK, of which approximately 3.1 million were diagnosed. Common agents for the treatment of RA include NSAIDs, DMARDs, biologic agents and corticosteroids such as prednisone. Physicians are increasingly supportive of prescribing multiple therapies as some RA patients are able to achieve a clinical remission with multiple treatments. A Medical Marketing Economics May 2008 study of 150 RA patients in the United States, which we sponsored, showed that despite the use of a combination of currently available treatments for RA, over 90% of the patients reported suffering from morning stiffness, pain and immobility.

In addition, according to the 2006 DataMonitor report, approximately 50% of RA patients in the United States, Japan, France, Italy, Spain, Germany and the UK are prescribed combination therapy which often includes corticosteroids, with prednisone being one of the most common. Corticosteroids, including prednisone, are used to suppress various autoimmune, inflammatory and allergic disorders by inhibiting the production of various pro-inflammatory cytokines, such as IL-6 and TNF-alpha. Joint inflammation in RA is driven by excessive production of inflammatory mediators and cytokines such as IL-6 and TNF-alpha. While corticosteroids are potent and effective agents to treat patients with RA, they are often used at high doses to treat RA flares or significant inflammation. High-dose oral corticosteroid treatment is not a viable long-term treatment option due to adverse side effects such as osteoporosis, cardiovascular disease and weight gain. However, clinical studies have shown that the long-term use of low-dose prednisone (<10 mg per day) does not dramatically increase total adverse events. In addition, low-doses, typically less than 10 mg daily, of corticosteroids such as prednisone have been shown to treat the symptoms of RA while slowing the overall progression of the disease.

An additional limitation of RA treatment with corticosteroids is related to the time at which patients’ pro-inflammatory cytokines are at peak levels. Increased levels of pro-inflammatory cytokines during the early morning hours are a known cause of morning stiffness and decreased mobility of RA. IL-6 levels are substantially increased in patients with RA in general and show a significant circadian variation in these levels. Peak IL-6 levels tend to occur in the early morning hours and low levels typically occur in the afternoon and evening. Therefore, we believe an optimal treatment would reduce IL-6 levels in the early morning hours.

Our Solutions

DUEXIS

DUEXIS is a proprietary single tablet formulation containing a fixed-dose combination of ibuprofen, the most widely prescribed NSAID, and famotidine, a well-established GI agent used to treat dyspepsia, gastroesophageal reflux disease, or GERD, and active ulcers, in one pill. Ibuprofen has proven anti-inflammatory and analgesic properties and famotidine reduces the stomach acid secretion that can cause upper GI ulcers. Both ibuprofen and famotidine have well documented and excellent long-term safety profiles and both products have been used for many years by millions of patients worldwide. Based on clinical study results, DUEXIS has been proven to reduce the risk of NSAID-induced upper GI ulcers.

Ibuprofen: One of the World’s Most Widely Prescribed NSAIDs

Ibuprofen continues to be one of the most widely prescribed NSAIDs worldwide. According to Intercontinental Marketing Services, or IMS, in the United States alone, there were over 38 million prescriptions written for ibuprofen in 2014. In the United States, both the 600 mg and 800 mg doses together account for approximately 88% of total ibuprofen prescriptions. In addition, ibuprofen’s flexible three times daily dosing allows it to be used for both chronic conditions such as arthritis and chronic back pain, and acute conditions such as sprains and strains.
Famotidine: A Safe and Effective GI Agent

Famotidine is the most potent marketed drug in the class of histamine-2 receptor antagonists, or H2RA. H2RA’s are a class of drugs used to block the action of histamine on the cells in the stomach that secrete gastric acid. Famotidine was chosen as the ideal GI protectant to be combined with ibuprofen as it is a well-studied compound with an estimated 18.8 million patients treated worldwide that provides distinct advantages including:

- rapid onset of action;
- significant reduction in gastric acid levels in the GI tract for the treatment of dyspepsia, GERD and NSAID-induced upper GI ulcers; and
- well tolerated with a low incidence of adverse drug reactions and a demonstrated safety margin of up to eight times the approved prescription dose for an extended period of greater than 12 months.

Despite these advantages, famotidine had not yet been approved to reduce the incidence of NSAID-induced upper GI ulcers in patients taking NSAIDs. We conducted two pivotal Phase 3 clinical trials demonstrating that treatment with DUEXIS significantly reduced the incidence of NSAID-induced upper GI ulcers in patients with mild to moderate pain or arthritis compared to ibuprofen alone. Based on the data from the Phase 3 clinical trials of DUEXIS, we submitted an NDA requesting approval to market DUEXIS in the United States in March 2010. On April 23, 2011, the FDA approved DUEXIS for the relief of signs and symptoms of RA and OA and to decrease the risk of developing upper GI ulcers in patients who are taking ibuprofen for these indications.

Benefits of a Fixed-Dose Combination Therapy

Numerous studies have demonstrated that fixed-dose combination therapy provides significant advantages over taking multiple pills. Specifically, fixed-dose combinations can reduce the number of pills, ensure that the correct dosage of each component is taken at the correct time and improve compliance, often associated with better treatment outcomes. DUEXIS has been formulated to provide an optimal dosing regimen of ibuprofen and famotidine together in the convenience of a single pill.

DUEXIS Commercial Status

DUEXIS is indicated for the relief of signs and symptoms of RA and OA and to decrease the risk of developing GI ulcers in patients who are taking ibuprofen for these indications. In the second half of 2011, we hired our initial commercial organization, including approximately 80 sales representatives, completed sales force training and began marketing DUEXIS to physicians in December 2011. Due to the continued prescription growth of DUEXIS and VIMOVO, and the acquisition of PENNSAID 2% in October 2014, the primary care commercial organization continues to grow. As of January 2015, we had approximately 325 primary care sales representatives marketing DUEXIS, VIMOVO and PENNSAID 2% to physicians in the United States.

In June 2012, we licensed DUEXIS rights in Latin America to Grünenthal, a private company focused on the promotion of pain products.

PENNSAID 2%

PENNSAID 2% is a topical NSAID that is applied directly to the knee and is indicated for the treatment of pain of OA of the knee(s). PENNSAID 2% contains diclofenac sodium, a commonly prescribed NSAID, to treat OA pain. PENNSAID 2% also includes DMSO, a powerful penetrating agent that helps ensure that diclofenac sodium is absorbed through the skin to the site of inflammation and pain. Topical NSAIDs such as PENNSAID 2% are an alternative to oral NSAID treatment because they reduce systemic exposure to a fraction of that provided by an oral NSAID. PENNSAID 2% is the only topical NSAID offered with the convenience of a metered-dose pump, which ensures that the patient will get the correct amount of PENNSAID 2% solution each time. PENNSAID 2% is easy to apply for patients because PENNSAID 2% is applied in two pumps, twice daily, delivering relief right to the site of OA knee pain.
Benefits of Topical NSAIDs

Within the NSAID market exists a significant niche for topical NSAIDs, which are prescribed over 5 million times per year. Topical NSAID treatment may be appropriate for some patients, such as patients who may benefit from the lower systemic exposure in a topical NSAID, patients with OA in just one joint such as the knee, patients who have trouble taking oral medications, or patients who are older.

PENNSAID 2% Commercial Status

On January 16, 2014, the FDA approved PENNSAID 2% for the treatment of the pain of OA of the knee(s). We acquired the U.S. rights to PENNSAID 2% on October 16, 2014 and began marketing PENNSAID 2% with our primary care sales force in early January 2015. As of January 2015, we had approximately 325 field sales representatives marketing DUEXIS, PENNSAID 2% and VIMOVO to physicians in the United States.

RAYOS/LODOTRA

RAYOS, known as LODOTRA outside the United States, is a proprietary delayed-release formulation of low-dose prednisone for the treatment of moderate to severe, active RA in adults particularly when accompanied by morning stiffness.

RAYOS/LODOTRA Solution

The proprietary formulation technology of RAYOS/LODOTRA enables a delayed-release of prednisone approximately four hours after administration. The RAYOS/LODOTRA proprietary delivery system synchronizes the prednisone delivery time with the patient’s elevated cytokine levels, thereby taking effect at a physiologically optimal point to inhibit cytokine production, and thus significantly reduces the signs and symptoms of RA and PMR.

RAYOS/LODOTRA was developed utilizing SkyPharma’s proprietary GeoClock™ and GeoMatrix™ technologies, for which we hold an exclusive worldwide license for the delivery of corticosteroids. RAYOS/LODOTRA is comprised of an active core containing prednisone, which is encapsulated by an inactive porous shell. The inactive shell acts as a barrier between the product’s active core and a patient’s GI fluids. RAYOS/LODOTRA is intended to be administered at bedtime. At approximately four hours following bedtime administration of RAYOS/LODOTRA, water in the digestive tract diffuses through the shell, causing the active core to expand, which leads to a weakening and breakage of the shell and allows the release of prednisone from the active core. Our pharmacokinetic studies have shown that the blood concentration of prednisone from RAYOS/LODOTRA is similar to immediate release prednisone except for the intended time delay of product release after administration.

RAYOS/LODOTRA Commercial Status

On July 26, 2012, the FDA approved RAYOS for the treatment of RA, PMR, PsA, AS, asthma, COPD and a number of other conditions. We focus our promotion of RAYOS in the United States on rheumatology indications, including RA and PMR. We began marketing RAYOS to a subset of U.S. rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of rheumatologists and high-value primary care physicians. LODOTRA received its first approval in Europe in March 2009 and is currently approved for marketing in over 30 countries outside the United States where Mundipharma holds the commercial rights.

RAYOS/LODOTRA in Other Indications

We also conducted a small Phase 2 clinical trial to evaluate the potential use of RAYOS/LODOTRA to treat severe asthma compared to immediate-release prednisone. Severe asthma sufferers are frequently prescribed very high doses of oral corticosteroids. However, high-dose oral corticosteroid treatment is limited by side effects which include, among others, osteoporosis and its various negative effects. Data from seven patients who had
been treated with 5 mg to 45 mg of daily immediate release prednisone in accordance with the study protocol showed improvements in nocturnal symptoms, asthma control and asthma-related quality of life when switched to an equivalent dose of RAYOS/LODOTRA.

**VIMOVO**

VIMOVO is a proprietary, fixed-dose, delayed-release tablet. VIMOVO combines enteric-coated naproxen, an NSAID, surrounded by a layer of immediate-release esomeprazole magnesium, a PPI, surrounding the core. Naproxen has proven anti-inflammatory and analgesic properties and esomeprazole magnesium reduces the stomach acid secretions that can cause upper GI ulcers. Both naproxen and esomeprazole magnesium have well-documented and excellent long-term safety profiles and both products have been used by millions of patients worldwide. Based on clinical trial results, VIMOVO has been shown to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.

**Naproxen: One of the World’s Most Widely Prescribed NSAIDs**

Naproxen is one of the most widely prescribed NSAIDs worldwide. According to IMS, in the United States alone, there were over 17 million prescriptions written for naproxen in 2014. In the United States, the 375 mg and 500 mg doses together account for approximately 96% of total naproxen prescriptions. In addition, naproxen’s twice daily dosing allows it to be used for chronic conditions such as arthritis and AS.

**Esomeprazole Magnesium: A Safe and Effective GI Agent**

Esomeprazole magnesium, a gastroprotective agent, is a PPI that works by inhibiting the secretion of gastric acid thus decreasing the amount of acid in the stomach. PPIs are considered to be very potent inhibitors of acid secretion. Esomeprazole magnesium is indicated for reducing the risk of NSAID-induced gastric ulcers.

**Benefits of a Fixed-Dose Combination Therapy**

VIMOVO is specifically formulated to allow esomeprazole magnesium to achieve its gastroprotective impact before naproxen is released into the system. VIMOVO’s design is intended to produce a sequential delivery of gastroprotective esomeprazole before exposure to naproxen.

**VIMOVO Commercial Status**

On April 30, 2010, the FDA approved VIMOVO delayed release tablets, 375 mg/20 mg and 500 mg/20 mg for relief of signs and symptoms of OA, RA and AS and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers. In December 2013, as a result of our acquisition of U.S. rights to VIMOVO, we began the expansion of our sales force to approximately 250 primary care representatives and 40 rheumatology sales specialists, all of which began marketing VIMOVO in early February 2014. Because of the continued prescription growth of VIMOVO and DUEXIS, and the addition of PENNSAID 2%, the Primary Care commercial organization continues to grow. As of January 2015, we had approximately 325 field sales representatives marketing DUEXIS, PENNSAID 2% and VIMOVO to physicians in the United States.

**ORPHAN DISORDERS**

**Market Opportunity**

**Chronic Granulomatous Disease**

CGD is a genetic disorder of the immune system. It is described as a primary immunodeficiency disorder, which means it is not caused by another disease or disorder. In people who have CGD, a type of white blood cell, called a phagocyte, is defective. These defective phagocytes cannot generate superoxide, leading to an inability to kill harmful microorganisms such as bacteria and fungi. As a result, the immune system is weakened. People with CGD are more likely to have certain problems such as recurrent severe bacterial and fungal infections and
chronic inflammatory conditions. These patients are prone to developing masses called granulomas, which can occur repeatedly in organs throughout the body and cause a variety of problems. CGD was first identified in the 1950s; since then CGD had changed from a disease of tragic and early complications to a disease of chronic management and high survival. Today, CGD is considered to be a condition that patients can live with and manage. Studies suggest overall survival has improved over the last decade with more patients living well into adulthood. Approximately 1 out of every 200,000 babies in the United States is born with CGD.

Severe, Malignant Osteopetrosis

There are several different forms of osteopetrosis (not to be confused with the more common osteoporosis, a very different condition), which are determined by their pattern of genetic inheritance and characteristics. All forms of osteopetrosis are characterized by an abnormal increase in bone density. SMO is one form of osteopetrosis and is sometimes referred to as marble bone disease or malignant infantile osteopetrosis because it occurs in very young children. SMO is a more severe form of malignant osteopetrosis. While exact numbers are not known, it has been estimated that 1 out of 250,000 children are born with SMO. Malignant in this instance does not refer to cancer. During normal bone development, existing bone material is constantly being replaced by new bone. Cells called osteoblasts cause new bone formation. Other cells called osteoclasts remove old bone through a process called resorption. In people with osteopetrosis, this balance is not maintained because their osteoclasts do not function properly. As a result, resorption of old bone material decreases while the formation of new bone continues. This leads to an abnormal increase in bone mass, which can make the bones more brittle. Because abnormal bone development affects many different systems in the body, osteopetrosis may cause problems such as blood disorders, decreased ability to fight infection, bone fractures, problems with vision and hearing, and abnormal appearance of the face and head.

Our Solution — ACTIMMUNE

ACTIMMUNE is a biologically manufactured protein called interferon gamma-1b that is similar to a protein the human body makes naturally. In the body, interferon gamma is produced by cells of the immune system and helps to prevent infection in patients with CGD and enhances osteoclast function in patients with SMO. ACTIMMUNE is approved by the FDA to reduce the frequency and severity of serious infections associated with CGD and for delaying time to disease progression in patients with SMO. The precise way that ACTIMMUNE works to help prevent infection in patients with CGD is not fully understood, but ACTIMMUNE is believed to work by modifying the cellular function of various cells, including those in the immune system. The precise way that ACTIMMUNE works to slow the worsening of SMO is also not fully understood, but ACTIMMUNE is believed to work by modifying the cellular function of various cells, including those that help form bones.

ACTIMMUNE Efficacy in CGD

The International Chronic Granulomatous Disease Cooperative Study Group, or ICGDSCG, conducted a controlled clinical trial in 128 patients (ages ranging from 1 to 44 years old) at 13 medical centers across 4 countries. The purpose of this clinical trial was to evaluate the safety and efficacy of ACTIMMUNE in reducing the frequency and severity of serious infections in patients with CGD. Patients enrolled in the trial were randomly selected to receive either ACTIMMUNE or placebo in addition to antibiotics. The number and timing of serious infections were tracked in all patients for up to 1 year. ACTIMMUNE was administered 3 times weekly using the same dosing regimen that is recommended today. The average duration of treatment was 8.9 months. The study was terminated early following demonstration of a highly statistically significant benefit of ACTIMMUNE therapy compared to placebo with respect to time to serious infection (p=0.0036), the primary endpoint of the investigation. The results of the trial were published in the New England Journal of Medicine. Compared with patients given placebo (n=65), patients in the ACTIMMUNE (n=63) group experienced:

- 67% reduction in relative risk of serious infections
- 67% fewer inpatient hospital days
- 64% reduction in the total number and rate of serious infections
As demonstrated in the clinical trial, a treatment benefit included a two-fold (53%) reduction in the number of CGD patients with at least one serious infection, defined as a clinical event requiring hospitalization and the use of parenteral antibiotics (ACTIMMUNE: 14/63 vs. placebo: 30/65; \( p=0.002 \)). The beneficial effect of ACTIMMUNE was demonstrated throughout a 12 month study, in which 77% of patients with CGD receiving ACTIMMUNE were free of serious infection during the study compared to 30% of patients who received placebo (\( p=0.0006 \)). The mean duration of therapy for these patients was 8.9 months.

Investigators concluded that ACTIMMUNE is an effective and safe therapy for patients with CGD, since the therapy statistically reduced the frequency of serious infections.

**ACTIMMUNE Efficacy in SMO**

In a controlled clinical trial, 16 patients were randomized to receive either ACTIMMUNE with calcitriol or calcitriol alone. The age of patients ranged from 1 month to 8 years; with a mean age of 1.5 years. The median time to progression in the ACTIMMUNE plus calcitriol arm was 165 days vs. a median of 65 days in the calcitriol only arm. In a separate analysis that combined data from a second trial, 19 of 24 patients on ACTIMMUNE therapy (+/- calcitriol) for at least 6 months had reduced trabecular bone volume compared to baseline.

**Safety of ACTIMMUNE**

The safety of ACTIMMUNE was also evaluated during the CGD clinical trial. Investigators from ICGDCSG concluded that there were no serious side effects directly attributed to the administration of ACTIMMUNE in patients with CGD during the trial. The most common side effects observed in patients with CGD given ACTIMMUNE were flu-like symptoms, such as fever, headache, and chills. The most common side effects seen with ACTIMMUNE are “flu-like” symptoms such as fever, headache, chills, myalgia (muscle pain), and fatigue, which may reduce in severity as treatment continues. Administering ACTIMMUNE at bedtime may also help minimize some of these symptoms. Acetaminophen may be helpful in preventing fever and headache.

ACTIMMUNE can cause severe allergic reactions and/or rash; flu-like symptoms, which may worsen pre-existing heart conditions; reversible changes to the nervous system (such as decreased mental status, walking disturbances, and dizziness); reversible severe bone marrow toxicity; decreased production of important cells in the body; and reversible changes to liver function (particularly in patients less than one year old).

**ACTIMMUNE Commercial Status**

ACTIMMUNE is the only drug currently approved by the FDA for the treatment for CGD and SMO and we currently market and distribute ACTIMMUNE only in the United States. Our licenses allow us to market and sell ACTIMMUNE in the United States, Canada and Japan. We also supply ACTIMMUNE to patients in Canada, if so requested by way of a prescription from their treating physicians, through Health Canada’s Special Access Program, which provides access to non-marketed drugs in Canada for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable or are unavailable. Sales in Canada are not material. We have not otherwise registered or sold ACTIMMUNE in any other territories for which it currently holds commercial rights.

**Potential for ACTIMMUNE in Friedreich’s Ataxia**

FA is a debilitating, life-shortening, degenerative, neuro-muscular disorder that affects approximately 3,700 individuals in the United States and 15,000 worldwide, according to the Friedreich's Ataxia Research Alliance, or FARA. On October 3, 2014, the FDA granted orphan-drug designation for ACTIMMUNE for the treatment of FA. The FDA has agreed to the primary endpoint for a planned Phase 3 study that will evaluate ACTIMMUNE in the treatment of FA. The study will be conducted in collaboration with the FARA, and the investigators of FARA’s Collaborative Clinical Research Network in Friedreich’s Ataxia. The primary endpoint
for the Phase 3 study will be the change from baseline after 26 weeks in the Friedreich’s Ataxia Rating Scale-modified neurological exam score (FARS-mNeuro) for patients treated with ACTIMMUNE compared to placebo. The study is planned to be a randomized, double-blind, multicenter, placebo-controlled, 26-week study evaluating ACTIMMUNE in children and young adults (10-25 years of age). It is anticipated that approximately 110 subjects will be screened at four U.S. centers for eligibility to randomize approximately 90 subjects 1:1 to receive either ACTIMMUNE or placebo. We anticipate the study will take 18 months to complete. In February 2015, we submitted an IND application and anticipate the Phase 3 clinical study will begin enrolling patients in the second quarter of 2015.

Commercial and Supply Agreements

ACTIMMUNE

Boehringer Ingelheim Manufacturing and Supply Agreement

In July 2013, Vidara and Boehringer Ingelheim entered into an exclusive supply agreement, which we assumed as of result of the Merger. Pursuant to the agreement, Boehringer Ingelheim manufactures the active drug substance and commercial quantities of the ACTIMMUNE finished drug product. Boehringer Ingelheim manufactures the active drug substance at its production facility in Vienna, Austria, and the finished drug product at its facility in Biberach an der Riss, Germany. Boehringer Ingelheim is our sole source supplier for ACTIMMUNE active drug substance and finished drug product. The processes used to manufacture and test ACTIMMUNE are complex and subject to FDA inspection and approval. The ACTIMMUNE active drug substance has a shelf life of 36 months from the date of manufacture and the ACTIMMUNE finished drug product has a shelf life of 36 months from the date of filling of the single-use vial. Boehringer Ingelheim also provides quality assurance testing for ACTIMMUNE. Under the terms of this agreement, we are required to purchase minimum quantities of finished drug product of 75,000 vials per annum. Boehringer Ingelheim manufactures our commercial requirements of ACTIMMUNE on an annual basis, and based on our forecasts and the annual contractual minimum purchase quantity. The supply agreement has a term that runs until July 31, 2020 and which can be further renewed by agreement between parties. Under this supply agreement, either we or Boehringer Ingelheim may terminate the agreement for an uncured material breach by the other party or upon the other party’s bankruptcy or insolvency.

Under a Development and Marketing Agreement with Boehringer Ingelheim, we are required to pay royalties on net sales in certain applicable markets in Latin America, Asia, Africa and Eastern Europe if we elect to commercialize ACTIMMUNE in those territories. To date, we have not pursued regulatory or other approvals or commercialized ACTIMMUNE in those territories.

Genentech and Connetics License Agreements

Under a license agreement with Genentech Inc., or Genentech, which was the original developer of ACTIMMUNE, we are or were obligated to pay royalties to Genentech on our net sales of ACTIMMUNE as follows:

- Through November 25, 2014, a royalty of 45% of the first $3.7 million in net sales achieved in a calendar year, and 10% on all additional net sales in that year;
- For the period from November 26, 2014 through May 5, 2018, the royalty payments will be reduced to a 20%-30% range for the first tier in net sales and in the 1%-9% range for the second tier; and
- From May 6, 2018 and for so long as the Company continues to commercially sell ACTIMMUNE, an annual royalty in the low single digits as a percentage of annual net sales.

Either Genentech or we may terminate the agreement if the other party becomes bankrupt or defaults, however, in the case of a default, the defaulting party has 30 days to cure the default before the license agreement may be terminated.
Under the terms of an agreement with Connetics Corporation (which was the predecessor parent company to InterMune and is now part of GlaxoSmithKline), or Connetics, we are obligated to pay royalties to Connetics on our net sales of ACTIMMUNE as follows:

- 0.25% of net sales of ACTIMMUNE, rising to 0.5% once cumulative net sales of ACTIMMUNE in the United States surpass $1.0 billion; and in the event we develop and receive regulatory approval for ACTIMMUNE in the indication of scleroderma, we will be obligated to pay a royalty of 4% on all net sales of ACTIMMUNE recorded for use in that indication.

Either Connetics or we may terminate the agreement if the other party becomes bankrupt or defaults, however, in the case of a default, the defaulting party has 30 days to cure the default before the license agreement may be terminated.

**DUEXIS**

**BASF Contract**

In July 2010, we entered into a contract with BASF Corporation, or BASF, for the purchase of DC85, which is ibuprofen in a direct compression blend and is the active ingredient in DUEXIS. Pursuant to the agreement, we are obligated to purchase a significant majority of our commercial demand for DC85 from BASF. The contract expires in December 2017. Thereafter, the agreement automatically renews for successive renewal terms of three years each until terminated by either party giving specified prior written notice to the other party. Either party may also terminate the agreement in the event of uncured breach by the other party. If the agreement terminates for any reason before a specified date and we have not purchased requisite amounts of DC85, BASF has the right to withhold from the pre-purchase credit an amount based upon the total amount of DC85 purchased throughout the life of the agreement.

**Manufacturing and Supply Agreement with sanofi-aventis U.S. LLC**

In May 2011, we entered into a manufacturing and supply agreement with sanofi-aventis U.S. Pursuant to the agreement, sanofi-aventis U.S. is obligated to manufacture and supply DUEXIS to us in final, packaged form, and we are obligated to purchase DUEXIS exclusively from sanofi-aventis U.S. for our commercial requirements of DUEXIS in North America and certain countries and territories in Europe, including the European Union member states and Scandinavia, and South America. Sanofi-aventis U.S. is obligated to acquire the components necessary to manufacture DUEXIS, including the active pharmaceutical ingredients, or APIs, DC85 and famotidine, and is obligated to acquire all DC85 under the terms of any agreements we may have with suppliers for the supply of DC85. We expect that sanofi-aventis U.S. will obtain DC85 from BASF Corporation through our sales contract with BASF and famotidine through our supply agreement with Dr. Reddy’s Laboratories. In order to allow sanofi-aventis U.S. to perform its obligations under the agreement, we granted sanofi-aventis U.S. a non-exclusive license to our related intellectual property. In November 2011, the FDA approved the use of the sanofi-aventis Canada Inc. manufacturing site in Laval, Quebec to manufacture DUEXIS. As a result of the FDA approval of the sanofi-aventis Canada, Inc. manufacturing site in Laval, Quebec, sanofi-aventis U.S. is the exclusive commercial manufacturer and supplier of DUEXIS. In December 2011, Valeant acquired Dermik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although, Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S. The price for DUEXIS under the agreement varies depending on the configuration and volume of DUEXIS we purchase and is subject to annual adjustments to reflect changes in costs as measured by the Producer Price Index published by the U.S. Department of Labor, Bureau of Labor Statistics and certain other changes and events set forth in the agreement. We have paid for the purchase and installation of equipment necessary to manufacture DUEXIS tablets, and sanofi-aventis U.S. is obligated to pay the costs of routine maintenance of the equipment. Upon expiration or termination of the agreement we may also be obligated to reimburse sanofi-aventis U.S. for the depreciated net book value of any other equipment purchased by sanofi-aventis U.S. in order to fulfill its obligations under the agreement.
The agreement term extends until the eighth anniversary of the first commercial sale of DUEXIS in any country in the territory and automatically extends for successive two year terms unless terminated by either party upon two years prior written notice. Either party may terminate the agreement upon 30 days’ prior written notice to the other party in the event of breach by the other party that is not cured within 30 days of notice (which notice period may be longer in certain, limited situations) or in the event we lose regulatory approval to market DUEXIS in all countries within the territory, and either party may terminate the agreement without cause upon two years prior written notice to the other party at any time after the third anniversary of the first commercial sale of DUEXIS in any country in the territory.

**Grünenthal Agreement**

In June 2012, we entered into a collaboration, license and supply agreement with Grünenthal for the potential commercialization of DUEXIS in certain Latin American and Caribbean countries. Under the terms of the agreement, we will supply DUEXIS to Grünenthal exclusively in the territory at an agreed upon price and they will have the exclusive right to distribute DUEXIS in the territory. Subject to early termination, the term of the agreement is 10 years from launch with certain automatic 2-year renewal provisions.

**PENNSAID 2%**

**Nuvo Supply Agreement**

In October 2014, in connection with the acquisition of the U.S. rights to PENNSAID 2% from Nuvo, we entered into an exclusive supply agreement with Nuvo. Under the supply agreement, Nuvo will manufacture and supply PENNSAID 2% to us. We have committed to a binding purchase order to Nuvo for delivery of PENNSAID 2%. In addition, at least 90 days prior to the first day of each calendar month during the term of the supply agreement, we are required to submit a binding written purchase order to Nuvo for PENNSAID 2% in minimum batch quantities. The initial term of our supply agreement is through December 31, 2022, but the agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party.

**RAYOS/LODOTRA**

**SkyePharma and Jagotec Agreements**

**Development and License Agreement**

In August 2004, we entered into a development and license agreement with SkyePharma and Jagotec, a wholly-owned subsidiary of SkyePharma, regarding certain proprietary technology and know-how owned by SkyePharma for the delayed release of corticosteroids. The agreement replaced a similar agreement entered into between Merck and SkyePharma in 1998, which Merck assigned to us.

Under the agreement, which was amended in August 2007, we received an exclusive, sub-licensable worldwide license to the oral formulation of any corticosteroid, including prednisone, prednisolone, methylprednisolone and/or cortisone, with delayed release technology covered by intellectual property rights and know-how owned by SkyePharma. We were also granted an option to acquire a royalty-free, exclusive and sub-licensable right to license and manufacture RAYOS/LODOTRA which we can exercise any time upon specified prior written notice, expiring no earlier than five years after the first launch of RAYOS/LODOTRA. We have exercised the option to acquire the manufacturing license, which became effective in April 2014.

In return for the grant of the license, Jagotec has the right to manufacture, package and supply RAYOS/LODOTRA to us in accordance with terms and conditions of a separate manufacturing and supply agreement we entered into with Jagotec. In addition, Jagotec is entitled to receive a single digit percentage royalty on net sales of RAYOS/LODOTRA and on any sub-licensing income, which includes any payments not calculated based on the net sales of RAYOS/LODOTRA, such as license fees, and lump sum and milestone payments.
The agreement expires on a country by country basis, upon the expiration of the last patent rights for RAYOS/LODOTRA, which will expire between 2024 and 2028. In the event of expiration, the licenses under the agreement will be perpetual, fully paid-up and royalty-free. Either party may also terminate the agreement in the event of a liquidation or bankruptcy of the other party or upon an uncured breach by the other party.

Manufacturing and Supply Agreement

In August 2007, we entered into a manufacturing and supply agreement with Jagotec for the purchase of RAYOS/LODOTRA. Under the agreement, which was amended in March 2011, Jagotec or its affiliates manufacture and supply RAYOS/LODOTRA to us in bulk. In August 2011, SkyePharma leased their entire pharmaceutical manufacturing business to Aenova, a large contract manufacturing organization, and Aenova is now a subcontractor for Jagotec for the manufacture of RAYOS/LODOTRA, with our consent. We were required to purchase RAYOS/LODOTRA exclusively from Jagotec through April 2014, after which we are able to purchase RAYOS/LODOTRA from other manufacturers if we choose. As of December 31, 2014 our total remaining minimum purchase commitment was approximately $3.3 million based on tablet pricing under the agreement as of that date, which amount is subject to volume and price adjustments due to, among other things, inflation, order quantities and launch and approval in certain European Union countries. We also supply the API, prednisone to Jagotec at our expense for use in the manufacture of RAYOS/LODOTRA.

We pay Jagotec, exclusive of any value added tax or similar governmental charges, a price for RAYOS/LODOTRA representing a negotiated mark-up over manufacturing costs. After a short initial period, the price will be adjusted annually to reflect changes in both manufacturing and materials costs as measured by the Ensemble price index. If Jagotec makes a major capital expenditure during the contract term to fulfill increased orders forecast by us, the price per unit will increase if the actual order falls short of the forecast.

The agreement term extends until the end of the fifth year after the first launch of RAYOS/LODOTRA and automatically extends on a yearly basis unless terminated by either party upon prior written notice. Either party may also terminate the agreement in the event of insolvency, liquidation or bankruptcy of the other party or upon an uncured breach by the other party. We have the right to receive a continuing supply of RAYOS/LODOTRA from Jagotec for a period of 24 months after termination by Jagotec, regardless of the reason for termination.

Pursuant to a letter agreement between Jagotec and us, Jagotec agreed to allow us to give Bayer Pharma AG, or Bayer, the right to manufacture, test and release quantities of RAYOS/LODOTRA in order to establish and maintain Bayer as a manufacturer of RAYOS/LODOTRA. Under certain circumstances, we may also purchase shortfall quantities of RAYOS/LODOTRA from Bayer to the extent Jagotec is unable to supply us. In March 2013, we entered into an agreement with Bayer to allow us to purchase quantities of RAYOS/LODOTRA for these purposes. After our manufacturing license from Jagotec becomes effective, we may also purchase quantities of RAYOS/LODOTRA from Bayer pursuant to our agreement with Bayer.

Merck Serono License Agreements (Assigned to Mundipharma Laboratories)

In December 2006 and March 2009, we entered into separate transfer, license and supply agreements with Merck Serono and Merck GesmbH, an affiliate of Merck Serono, for the commercialization of LODOTRA in Germany and Austria, respectively. The agreement covering Germany was amended in December 2008 to allow co-promotion of LODOTRA in Germany. Under the agreements, we granted Merck Serono and Merck GesmbH exclusive distribution and marketing rights pertaining to LODOTRA for each of Germany and Austria, respectively, and an exclusive license to use the trademark for LODOTRA in Germany and Austria. The transfer, license and supply agreements related to Germany and Austria were assigned to Mundipharma Laboratories from Merck Serono and Merck GesmbH in April 2011 and September 2011, respectively, with our consent. Mundipharma Laboratories is obligated to commercialize LODOTRA in Germany and Austria, as applicable, exclusively under the LODOTRA trademark. Mundipharma Laboratories is obligated to use commercially reasonable efforts to market LODOTRA in Germany and Austria, and is prohibited from launching other oral corticosteroids for the treatment of RA for the first three years following the launch of LODOTRA. With respect
to the agreement covering Germany, if Mundipharma Laboratories does not meet specified minimum sales targets over specified periods of time, the marketing rights to LODOTRA will become nonexclusive unless Mundipharma Laboratories pays us the shortfall. With respect to the agreement covering Austria, if Mundipharma Laboratories does not meet specified minimum sales targets over specified periods of time, after good faith discussions to modify the agreement, we have the right to terminate the agreement.

Mundipharma Laboratories has agreed to purchase LODOTRA commercial product exclusively from us. We supply LODOTRA to Mundipharma Laboratories at the price which is the higher of (1) a percentage of the list price of LODOTRA sold to final purchasers of LODOTRA from Mundipharma Laboratories (excluding any discounts) and (2) the costs we incur for the production and delivery of LODOTRA to a Mundipharma Laboratories supply depot, as applicable, plus a profit mark-up.

Subject to early termination, the terms of the agreements are 15 years from the launch of LODOTRA in Germany and 10 years from the launch of LODOTRA in Austria. Thereafter, the agreements automatically renew until terminated by a party by giving specified prior written notice to the other party to the agreement. Under both agreements a party may also terminate an agreement in the event of a bankruptcy of the other party, certain events beyond the parties’ control that impair performance under an agreement, or upon material uncured breach by a party.

Mundipharma Agreements

In March 2009, we entered into a distribution agreement with Mundipharma for the commercialization of LODOTRA in Europe, excluding Germany and Austria, and a manufacturing and supply agreement with Mundipharma Medical. The distribution agreement, which was amended in July 2009 and March 2011, provides for an upfront payment of 5.0 million Euros, all of which has been paid by Mundipharma, and aggregate potential milestone payments of up to an additional 11.0 million Euros, which includes a credit in the amount of 1.0 million Euros we agreed to provide to Mundipharma to be applied towards certain future milestone payments in connection with the March 2011 amendment. As of December 31, 2014, we had received 4.9 million Euros in milestone payments under the distribution agreement.

Under the distribution agreement, we granted Mundipharma the exclusive distribution and marketing rights pertaining to LODOTRA for: Albania, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Israel, Italy, Latvia, Liechtenstein, Lithuania, Luxemburg, Macedonia, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, former Soviet Union countries, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the UK. We also granted Mundipharma an exclusive license to use our trademark for LODOTRA in these countries, and Mundipharma is allowed to commercialize LODOTRA under the LODOTRA trademark. Mundipharma is obligated to use commercially reasonable efforts to market LODOTRA in the territory and is prohibited from launching other oral corticosteroids during the term of the distribution agreement. If Mundipharma does not meet specified minimum sales targets, which range from single digit millions of Euros to tens of millions of Euros on a country by country basis, over specified periods of time, the marketing rights granted under the distribution agreement will become nonexclusive with respect to the applicable country unless Mundipharma pays us the shortfall.

Under the manufacturing and supply agreement, which was subsequently amended in March 2011, Mundipharma Medical agreed to purchase LODOTRA exclusively from us with respect to the territory. We supply LODOTRA to Mundipharma Medical at the price which is a specified percentage of the average net selling price for sales in a given country.

Subject to early termination, the terms of both of the March 2009 agreements extend to March 2024. Thereafter, the agreements automatically renew until terminated by either party giving specified prior written notice to other party. Either party may also terminate either of the agreements in the event of a bankruptcy of the other party or upon an uncured material breach by the other party. In addition, Mundipharma has the right to
In November 2010, we entered into a second distribution agreement with Mundipharma for the commercialization of LODOTRA in several Asian countries, Australia, New Zealand and South Africa, and a second manufacturing and supply agreement with Mundipharma Medical. Under the distribution agreement, we received an upfront payment of $3.5 million and may be entitled to additional aggregate milestone payments of up to $4.5 million. In March 2012, we amended the distribution agreement and the manufacturing and supply agreement to include certain Latin American countries. Under the March 2012 amendment to the distribution agreement, we may receive aggregate upfront and milestone payments of up to $2.0 million. In October 2013, we amended the distribution agreement and the manufacturing and supply agreement to include an additional 55 countries in the Middle Eastern and African regions. In September 2014, we further amended the distribution agreement and the manufacturing and supply agreement to include Cambodia, Myanmar, Laos and Brunei. As of December 31, 2014, under our distribution agreement we had received $0.2 million in milestone payments and $1.2 million associated with an upfront payment under the March 2012 amendment.

Under the distribution agreement, as amended, we granted Mundipharma the exclusive distribution and marketing rights pertaining to LODOTRA for: Australia, China, Hong Kong, Indonesia, Korea, Malaysia, New Zealand, the Philippines, Singapore, South Africa, Taiwan, Thailand, Vietnam, México, Brazil, Argentina, Colombia, Venezuela, Peru, Chile, Ecuador, Dominican Republic, Guatemala, Costa Rica, Uruguay, Bolivia, Panama, Nicaragua, El Salvador, Honduras and the Middle Eastern and African regions. Mundipharma will be responsible for obtaining regulatory approvals in these countries. We also granted Mundipharma an exclusive license to use our trademark for LODOTRA in these countries, and Mundipharma is allowed to commercialize LODOTRA under the LODOTRA trademark. Mundipharma is obligated to use commercially reasonable efforts to obtain regulatory approval for and market LODOTRA and is prohibited from launching other oral corticosteroids in these countries during the term of the distribution agreement. If Mundipharma does not meet specified minimum volume targets, which range from thousands of tablets of product to millions of tablets of product on a country by country basis, over specified periods of time, the marketing rights granted under the distribution agreement will become nonexclusive with respect to the applicable country unless Mundipharma pays us the shortfall.

Under the manufacturing and supply agreement, as amended, Mundipharma Medical agreed to purchase LODOTRA exclusively from us with respect to the territories. We supply bulk product of LODOTRA to Mundipharma Medical at an adjustable price per tablet and Mundipharma is responsible for final packaging and distribution in the territory.

Subject to early termination, the terms of both of the November 2010 agreements are 15 years from the first product launch on a country by country basis. Thereafter, the agreements automatically renew until terminated by either party by giving specified prior written notice to other party. Either party may terminate either of the agreements early in the event of a change in control of the other party, bankruptcy of the other party, or upon an uncured material breach by the other party. Either party has the right to terminate the distribution agreement with respect to any country upon prior written notice if the volume target is not met in such country for reasons beyond its control. In addition, Mundipharma has the right to terminate the distribution agreement in the event of material risk of personal injury to third parties or immediately by written notice with respect to any country if the market authorization for LODOTRA is cancelled, withdrawn or suspended in such country. We also have the right, subject to certain conditions, to terminate the distribution agreement with respect to any country in the territory if within a specified period of time, Mundipharma fails to submit appropriate filings to obtain marketing authorization in the country or fails to initiate a clinical trial required for marketing authorization in the country.

**Temmler Supply Agreement**

We have entered into an agreement with Temmler Werke GmbH, or Temmler, for the packaging and assembling of RAYOS/LODOTRA. Pursuant to the agreement, we may order RAYOS/LODOTRA according to
specified rolling forecasts. There are no minimum purchase requirements under the agreement and we may enter into agreements with other third-party packagers for RAYOS/LODOTRA. Subject to early termination, the agreement will remain in effect until December 21, 2015. Thereafter, the agreement automatically renews for additional one year periods unless either party provides notice to the other party at least twelve months prior to the expiration of the then-current period. Either party may also terminate the agreement at any time for an uncured material breach. In December 2013, Temmler provided us notice of termination. Therefore, subject to early termination, the agreement will terminate on December 21, 2015. In December 2012, Temmler was acquired by Aenaova Group.

**VIMOVO**

*AstraZeneca Asset Purchase Agreement*

In November 2013, we entered into an asset purchase agreement with AstraZeneca pursuant to which we acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs in the United States. Pursuant to the transactions contemplated by the asset purchase agreement, we acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the IND and NDA for VIMOVO in the United States, AstraZeneca’s interest in certain patents covering VIMOVO in the United States and certain promotional materials and records related to VIMOVO in the United States. Under the asset purchase agreement, we are also entitled to the benefit of a covenant not to sue granted by Merck Sharp & Dohme Corp. and certain of its affiliates, or collectively Merck, to AstraZeneca but exclusively licensed to Merck, that cover the manufacture and commercialization of VIMOVO in the United States. In addition, under the asset purchase agreement, AstraZeneca assigned to us its amended and restated collaboration and license agreement for the United States with Pozen, pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States. The terms of the amended and restated collaboration and license agreement for the United States with Pozen, or the Pozen license agreement, are described below.

In November 2013, in connection with the closing of the transactions contemplated by the asset purchase agreement, we also entered into a license agreement with AstraZeneca, a supply agreement with AstraZeneca’s affiliate, AstraZeneca LP, and certain other agreements that are described below. We also executed a transition agreement with AstraZeneca pursuant to which AstraZeneca transitioned to us regulatory and commercial responsibility for VIMOVO in the United States. From the closing of the transaction until December 31, 2013, AstraZeneca continued to commercialize VIMOVO in the United States under AstraZeneca’s existing pricing and paid to us the net profits recognized on sales of VIMOVO in the United States. Beginning January 1, 2014, we commenced commercialization of VIMOVO in the United States on our own behalf and under new pricing for VIMOVO.

In consideration for the U.S. rights to VIMOVO, we paid to AstraZeneca a one-time upfront cash payment of $35.0 million.

Following the closing of the transactions contemplated by the asset purchase agreement, we became responsible for and control matters relating to VIMOVO in the United States, including responsibility for commercialization of VIMOVO in the United States, responsibility for ongoing developmental and regulatory activities with respect to VIMOVO in the United States and responsibility for the current VIMOVO litigation with respect to the patents we purchased under the asset purchase agreement and the patents we licensed from Pozen under the Pozen license agreement. AstraZeneca continues to be responsible for and retains control of VIMOVO outside the United States.
In November 2013, in connection with the closing of the transactions contemplated by the asset purchase agreement, we entered into a license agreement with AstraZeneca, or the AstraZeneca license agreement, pursuant to which AstraZeneca granted us an exclusive license under certain intellectual property (including patents, know-how, trademarks, copyrights and domain names) of AstraZeneca and its affiliates to develop, manufacture and commercialize VIMOVO in the United States. AstraZeneca also granted us a non-exclusive license under certain intellectual property of AstraZeneca and its affiliates to manufacture, import, export and perform research and development activities with respect to VIMOVO outside the United States but solely for purposes of commercializing VIMOVO in the United States. In addition, AstraZeneca granted us a non-exclusive right of reference and use under certain regulatory documentation controlled by AstraZeneca and its affiliates to develop, manufacture and commercialize VIMOVO in the United States and to manufacture, import, export and perform research and development activities with respect to VIMOVO outside the United States but solely for purposes of commercializing VIMOVO in the United States.

Under the AstraZeneca license agreement, we granted AstraZeneca a non-exclusive sublicense under such licensed intellectual property and a non-exclusive right of reference under certain regulatory documentation controlled by us to manufacture, import, export and perform research and development activities with respect to VIMOVO in the United States but solely for purposes of commercializing VIMOVO outside the United States.

Under the AstraZeneca license agreement, we and our affiliates are subject to certain limitations and restrictions on our ability to develop, commercialize and seek regulatory approval with respect to VIMOVO or other products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs (excluding DUEXIS). These limitations and restrictions include, among other things, restrictions on indications for which we may commercialize VIMOVO or any such other products, restrictions on our ability to develop or seek regulatory approval with respect to such other products that contain esomeprazole, restrictions on our ability to develop or seek regulatory approval for VIMOVO for any indications other than the indications for which NSAIDs are indicated, and restrictions on our marketing activities with respect to VIMOVO and any such other products.

The AstraZeneca license agreement continues in full force and effect until terminated in accordance with its terms. Under the AstraZeneca license agreement, the parties may terminate upon mutual written agreement by the parties, or either party may terminate rights granted to us with respect to licensed trademarks and licensed domain names under the AstraZeneca license agreement upon uncured material breach by the other party of certain specified provisions of the AstraZeneca license agreement.

Amended and Restated Collaboration and License Agreement with Pozen; Letter Agreement with AstraZeneca and Pozen

Under the Pozen license agreement, Pozen granted us an exclusive, royalty-bearing license under certain of Pozen’s intellectual property in the United States to manufacture, develop and commercialize VIMOVO and other products controlled by us that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs, excluding DUEXIS, in the United States.

Under the Pozen license agreement, we are required to pay Pozen a flat 10% royalty based on net sales of VIMOVO and such other products sold by us, our affiliates or sublicensees during the royalty term, subject to minimum annual royalty obligations of $5.0 million in 2014 and $7.5 million each year thereafter, which minimum royalty obligations will continue for each year during which one of Pozen’s patents covers such products in the United States and there are no competing products in the United States. The royalty rate may be reduced to a mid-single digit royalty rate as a result of loss of market share to competing products. Our obligation to pay royalties to Pozen will expire upon the later of (a) expiration of the last-to-expire of certain patents covering such products in the United States, and (b) ten years after the first commercial sale of such products in
the United States. In addition, we will be obligated to reimburse Pozen for costs, including attorneys’ fees, incurred by Pozen in connection with VIMOVO patent litigation moving forward, subject to agreed caps.

We are responsible for, and are required to use diligent and reasonable efforts directed to commercializing VIMOVO or another qualified product in the United States. We will also own and maintain all regulatory filings and marketing approvals in the United States for any such products, including all INDs and NDAs for VIMOVO. Pozen covenanted that it will not at any time prior to the expiration of the royalty term, and will ensure that its affiliates do not, directly or indirectly, develop or commercialize or license any third party to develop or commercialize certain competing products in the United States.

The Pozen license agreement, unless earlier terminated, will expire upon expiration of the royalty term for all such products in the United States. Either party has the right to terminate the agreement upon uncured material breach by the other party or upon the bankruptcy or similar proceeding of the other party. We also have the right to terminate the Pozen license agreement for cause upon certain defined product failures.

In November 2013, in connection with the asset purchase agreement and the Pozen license agreement, we, AstraZeneca and Pozen entered into a letter agreement in which Pozen consented to AstraZeneca’s assignment of the Pozen license agreement to us and that addresses the rights and responsibilities of the parties in relation to the Pozen license agreement and the amended and restated collaboration and license agreement between Pozen and AstraZeneca for territories outside the United States, or the Pozen-AstraZeneca license agreement. Under the letter agreement, we and AstraZeneca agreed to pay Pozen milestone payments upon the achievement by us and AstraZeneca, collectively, of certain annual aggregate global net sales thresholds ranging from $550.0 million to $1.25 billion with respect to products licensed by Pozen to us under the Pozen license agreement and to AstraZeneca under the Pozen-AstraZeneca license agreement. The aggregate milestone payment amount that may be owed by AstraZeneca and us, collectively, under the letter agreement is $260.0 million, with the amount payable by each of us and AstraZeneca with respect to each milestone to be based upon the proportional sales achieved by each of us and AstraZeneca, respectively, in the applicable year.

The letter agreement will terminate with respect to Pozen and us upon the termination of the Pozen license agreement and will terminate with respect to Pozen and AstraZeneca upon the termination of the Pozen-AstraZeneca license agreement.

AstraZeneca Supply Agreement

In November 2013, in connection with the asset purchase agreement, we entered into a supply agreement with AstraZeneca pursuant to which AstraZeneca agreed to supply VIMOVO to us for commercialization in the United States. Under the supply agreement, AstraZeneca supplied the quantity of VIMOVO that we ordered, both for our own use and for use by our sublicensees, on a transitional basis through December 31, 2014. The supply agreement expired on December 31, 2014 and we have transitioned to Patheon for the manufacturing and supply of VIMOVO.

Patheon Agreement

In November 2013, we entered into a master manufacturing services agreement and product agreement, or, collectively, the Patheon manufacturing agreement, with Patheon, who is AstraZeneca’s contract manufacturer of VIMOVO, for the manufacture and supply of VIMOVO. Under the Patheon manufacturing agreement, we agreed to purchase a specified percentage of our VIMOVO requirements for the United States from Patheon or its affiliates. In addition, under the terms of the Patheon manufacturing agreement, we are able to enter into individual product agreements with Patheon for the manufacture of specific products in addition to VIMOVO if agreed by us and Patheon.

Pursuant to the Patheon manufacturing agreement, we are required to supply Patheon with any active materials for VIMOVO. We must pay an agreed price for final, packaged VIMOVO supplied by Patheon as set
forth in the Patheon manufacturing agreement, subject to adjustments, including certain unilateral adjustments by Patheon, such as annual adjustments for inflation and adjustments to account for certain increases in the cost of components of VIMOVO other than active materials.

The Patheon manufacturing agreement will be effective until December 31, 2019 and will automatically renew for successive terms of three years each if there is any product agreement in effect, unless either party gives written notice to the other party of its intention to terminate the agreement at least 24 months prior to the end of the then current term. Either party may terminate the Patheon manufacturing agreement or any product agreement early for uncured material breach by the other party or upon the other party’s bankruptcy or insolvency. We may terminate any product agreement if any regulatory authority takes any action or raises any objection that prevents us from commercializing the product. Additionally, Patheon may terminate the Patheon manufacturing agreement or any product agreement early if we assign our rights or obligations under the Patheon manufacturing agreement or such product agreement to a competitor of Patheon or to a party that, in the reasonable opinion of Patheon, is not a credit worthy substitute for us, or in certain other circumstances where we assign the Patheon manufacturing agreement or product agreement without Patheon’s consent.

Sales and Marketing

Our current sales force is approximately 375 sales representatives consisting of 325 primary care sales representatives and 50 sales representatives in specialty and orphan diseases business areas. In June 2012, to increase the number of called-on physicians for DUEXIS and in anticipation of the potential FDA approval of RAYOS, we expanded our sales force from 80 sales representatives to approximately 150 sales representatives. In December 2013, as a result of the acquisition of U.S. rights to VIMOVO from AstraZeneca, we further expanded our sales force to approximately 290, consisting of 250 primary care representatives and 40 rheumatology sales specialists and began marketing VIMOVO in early February 2014. As a result of the Merger, following which we began marketing ACTIMMUNE, and our recent acquisition of PENNSAID 2%, our sales force has increased to a total of approximately 375. Our primary care representatives are now marketing DUEXIS, PENNSAID 2% and VIMOVO. Our orphan sales force focuses on marketing to a limited number of healthcare practitioners who specialize in fields such as pediatric immunology, allergy, infectious diseases and hematology/oncology to help them understand the potential benefits of ACTIMMUNE for their patients with CGD and SMO. We announced the availability of Horizon-labeled PENNSAID 2% in the United States on January 2, 2015. We have, and expect to continue to, entered into agreements with third parties for commercialization of our products outside the United States.

In December 2014, we began execution of a comprehensive plan creating a new organization focused on the acceleration of our PME program to ensure continued growth of our NSAID portfolio in 2015. Through this program, physicians can have their patients’ prescriptions for our products shipped directly to the patient. Because the patient out of pocket cost for our products when dispensed through the PME program may be significantly lower than such costs when our products are dispensed outside of the PME program, prescriptions filled through our PME program are therefore less likely to be subject to the efforts of traditional pharmacies to switch a physician’s intended prescription of our products to a generic or over the counter brand. We expect that continued adoption of our PME program by physicians will be important to our ability to gain market share for our products as pressure from healthcare payors and pharmacy benefit managers, or PBMs, to use less expensive generic or over the counter brands instead of branded products increases.

Intellectual Property

Our objective is to aggressively patent the technology, inventions and improvements that we consider important to the development of our business. We have a portfolio of patents and applications based on clinical and pharmacokinetic/pharmacodynamic modeling discoveries, and our novel formulations. In addition, we have an exclusive license to pending U.S. and foreign patent applications from SkyePharma. We also have licenses to U.S.
We will only be able to protect our technologies and products from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them. As such, our commercial success will depend in part on receiving and maintaining patent protection and trade secret protection of our technologies and products as well as successfully defending these patents against third-party challenges.

On July 15, 2013, we received a Paragraph IV Patent Certification from Watson Laboratories, Inc. — Florida, known as Actavis Laboratories FL, Inc., or Watson, advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA’s review of its filing. On August 26, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against WLF seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124, and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg, and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. We, together with Jagotec have granted WLF a covenant not to sue with respect to US Patent Nos. 6,677,326 and 8,168,218, respectively, and accordingly these patents have been dismissed from the lawsuit. The Court held a claim construction hearing on October 16, 2014, and issued its opinion and order on claim construction on November 10, 2014, adopting our proposed construction of both of the disputed claim terms. The Court has scheduled expert discovery in the WLF action to be completed by June 2, 2015, and has set the pretrial conference for September 10, 2015. The trial date will be set following the pretrial conference.

On November 13, 2014, we received a Paragraph IV Patent Certification from Watson advising that Watson had filed an ANDA with the FDA for a generic version of PENNSAID 2%. Watson has not advised us as to the timing or status of the FDA’s review of its filing. On December 23, 2014, we filed suit in the United States District Court for the District of New Jersey against Watson seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that Watson has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Watson’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The Courts have not yet set trial dates for the Paddock actions.

On December 2, 2014, we received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,741,956 from Paddock Laboratories, LLC, or Paddock, advising that Paddock had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On January 9, 2015, we received from Paddock another Paragraph IV Patent Certification against newly Orange Book listed U.S. Patent No. 8,871,809. Paddock has not advised us as to the timing or status of the FDA’s review of its filing. On January 13, 2015 and January 14, 2015, we filed suit in the United States District Court for the District of New Jersey and the United States District Court for the District of Delaware, respectively, against Paddock seeking an injunction to prevent the approval of the ANDA. The lawsuits alleged that Paddock has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID 2% prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Paddock’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The Courts have not yet set trial dates for the Paddock actions.
Currently, patent litigation is pending in the United States District Court for the District of New Jersey against four generic companies intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the United States District Court for the District of New Jersey and have been consolidated for discovery purposes. They are collectively known as the VIMOVO cases, and involve the following sets of defendants: (i) Dr. Reddy’s; (ii) Lupin; (iii) Mylan; and (iv) Actavis. Patent litigation in the United States District Court for the District of New Jersey against a fifth generic company, Anchen, was dismissed on June 9, 2014 after Anchen recertified under Paragraph III. We understand that Dr. Reddy’s has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy’s is now able to commercialize VIMOVO under AstraZeneca’s Nexium patent rights. The settlement agreement, however, has no effect on the Pozen VIMOVO patents, which are still the subject of patent litigations. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

The VIMOVO cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, January 4, 2013, May 10, 2013, June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We understand the Dr. Reddy’s notice letters were dated March 11, 2011 and November 20, 2012; the Lupin notice letters were dated June 10, 2011 and March 12, 2014; the Mylan notice letter was dated May 16, 2013; the Actavis notice letters were dated March 29, 2013 and November 5, 2013; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order and has set a pretrial schedule but has not yet set a trial date.

On or about December 19, 2014, we filed a Notice of Opposition to a European patent, EP 2611457, to Roberto Testi, et al., covering compositions and methods for treating FA with interferon gamma, e.g., ACTIMMUNE. In the European Union, the grant of a patent may be opposed by one or more private parties.

On February 2, 2015, we received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, and 8,871,809 from Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd., or collectively Taro, advising that Taro had filed an ANDA with the FDA for a generic version of PENNSAID 2%. Taro has not advised us as to the timing or status of the FDA’s review of its filing. We are still in the process of evaluating the Paragraph IV Patent Certification, and it is anticipated we will file suit against Taro within the statutorily prescribed 45 day time limit.

We intend to vigorously defend our intellectual property rights relating to ACTIMMUNE, DUEXIS, PENNSAID 2%, RAYOS and VIMOVO, but we cannot predict the outcome of the WLF matter related to RAYOS or the DRL cases, the Mylan cases or the Watson cases related to VIMOVO, or the Watson and Paddock cases related to PENNSAID 2%. Any adverse outcome in these matters or any new generic challenges that may arise could result in one or more generic versions of ACTIMMUNE, DUEXIS, PENNSAID 2%, RAYOS and/or VIMOVO, being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to increase sales of ACTIMMUNE, DUEXIS, PENNSAID 2%, RAYOS and/or VIMOVO and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

In the United States, in addition to any patent protection, DUEXIS, PENNSAID 2%, RAYOS and VIMOVO, have been granted three years of marketing exclusivity as a Section 505(b)(2) NDA. This marketing exclusivity period for each product began upon marketing approval of such product and runs in parallel with any patents that have issued or we expect to be issued protecting such product. In the European Union, LODOTRA has received 10 years of marketing exclusivity protection, beginning with its March 2009 marketing authorization in Germany. We anticipate that DUEXIS will also receive 10 years of marketing exclusivity upon European approval on a country by country basis.
The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example:

- we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- we or our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our pending patent applications or the pending patent applications of our licensors will result in issued patents;
- our issued patents and the issued patents of our licensors may not provide a basis for commercially viable drugs, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties;
- we may not be successful in any patent litigation to enforce our patent rights, including our pending patent litigation regarding, PENNSAID 2%, RAYOS and/or VIMOVO;
- we may not develop additional proprietary technologies or product candidates that are patentable; or
- the patents of others may have an adverse effect on our business.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical companies and generic drug companies, although we are not currently aware of any other delayed release prednisone drug, ibuprofen/famotidine combination drug or naproxen/esomeprazole magnesium combination drug in development. We believe that the key competitive factors that will affect the commercial success of ACTIMMUNE, DUEXIS, PENNSAID 2%, RAYOS/LODOTRA and/or VIMOVO, as well as future drug candidates that we may develop, are efficacy, safety and tolerability profile, convenience in dosing, price and reimbursement.

**DUEXIS and VIMOVO**

DUEXIS and VIMOVO compete with other branded NSAIDs, including Celebrex, marketed by Pfizer Inc. Celebrex is an NSAID that selectively inhibits the COX-2 enzyme and is an effective anti-arthritic agent that reduces the risk of ulceration compared to traditional NSAIDs such as ibuprofen.

In general, DUEXIS and VIMOVO also face competition from the separate use of NSAIDs for pain relief and ulcer medications to address the risk of NSAID-induced ulcers. Use of these therapies separately in generic form may be less expensive than DUEXIS and VIMOVO. In addition, physicians could begin to prescribe both an NSAID and a GI protectant to be taken together but in separate pills. We expect to compete with the separate use of NSAIDs and ulcer medications primarily through DUEXIS’ and VIMOVO’s advantages in dosing convenience and patient compliance, and by educating physicians about such advantages, including through funding we have provided for the American Gastroenterology Association to help physicians and patients better understand and manage NSAID risks. We expect DUEXIS will be the only product containing a histamine-2 receptor antagonist with an indication to reduce the risk of NSAID-induced upper GI ulcers and that VIMOVO will be the only product containing a PPI with an indication to reduce the risk of NSAID-induced ulcers.
ACTIMMUNE

ACTIMMUNE presently faces little competition. ACTIMMUNE is the only drug currently approved by the FDA specifically for the treatment for CGD and SMO. While there are additional or alternative approaches used to treat patients with CGD and SMO, there are currently no products on the market that compete directly with ACTIMMUNE.

PENNSAID 2%

PENNSAID 2% faces competition from generic versions of PENNSAID 1.5% which are priced significantly less than the price we charge for PENNSAID 2%. In addition, PENNSAID 2% competes with two other branded topical NSAIDs, including Voltaren® Gel, marketed by Endo Pharmaceuticals, which is the market leader in the topical NSAID category. We expect to compete with these other products primarily through PENNSAID 2%’s dosing convenience and patient compliance. Unlike the other two products that are dosed four times per day and require the patient to measure out the correct dose, only PENNSAID 2% is easy to apply with the convenience of twice-daily dosing and a metered-dose pump, which ensures that the patient will get the correct amount of PENNSAID 2% solution each time.

RAYOS/LODOTRA

RAYOS/LODOTRA competes in Europe and in the United States with a number of products on the market to treat RA, including corticosteroids, such as prednisone, traditional DMARDs, such as methotrexate and biologic agents, such as HUMIRA and Enbrel. The majority of RA patients, however, are treated with DMARDs. DMARDs, such as methotrexate, are typically used as initial therapy in patients with RA whereas biologic agents are typically added to DMARDs as combination therapy. It is common for an RA patient to take a combination of a DMARD, an oral glucocorticoid, an NSAID and/or a biologic agent.

Manufacturing

All of our products are currently supplied by contract manufacturers. All manufacturing facilities contracted by us are registered with the FDA, European Medicines Agency, or EMA, and other internationally recognized regulatory authorities. In addition, these facilities have been audited by these agencies to confirm compliance. We do not at this time plan to build manufacturing facilities and currently plan to continue to scale our operations using contract manufacturers.

ACTIMMUNE

ACTIMMUNE, interferon gamma-1b, is a recombinant protein that is produced by fermentation of a genetically engineered Escherichia coli bacterium containing the DNA which encodes for the human protein. Purification of the active drug substance is achieved by conventional column chromatography. The resulting active drug substance is then formulated as a highly purified sterile solution and filled in a single-use vial for subcutaneous injection, which is the ACTIMMUNE finished drug product. In support of its manufacturing process, we and Boehringer Ingelheim store multiple vials of the Escherichia coli bacterium master cell bank and working cell bank in order to ensure that it will have adequate backup should any cell bank be lost in a catastrophic event.

We have an exclusive supply agreement with Boehringer Ingelheim to manufacture the active drug substance and commercial quantities of ACTIMMUNE finished drug product. Boehringer Ingelheim manufactures the active drug substance at its production facility in Vienna, Austria, and the finished drug product at its facility in Biberach an der Riss, Germany. Boehringer Ingelheim also provides us quality assurance testing for ACTIMMUNE. The processes used to manufacture and test ACTIMMUNE are complex and subject to FDA inspection and approval. The ACTIMMUNE active drug substance has a shelf life of 36 months from the date of manufacture and the ACTIMMUNE finished drug product has a shelf life of 36 months from the date of filling of
the single-use vial. Under the terms of this agreement, we are required to purchase minimum quantities of finished drug product of 75,000 vials per annum. Boehringer Ingelheim manufactures our commercial requirements of ACTIMMUNE on an annual basis, and based on our forecasts and the annual contractual minimum purchase quantity. The supply agreement has a term that runs until July 31, 2020 and which can be further renewed by agreement between parties.

**DUEXIS**

The DUEXIS manufacturing process is well-established and we validated the process in accordance with regulatory requirements prior to commercialization in the United States. We have contracted with internationally recognized pharmaceutical companies with operations in North America and Europe for contract manufacturing and packaging. In May 2011, we entered into a long-term supply and manufacturing agreement with sanofi-aventis U.S. for the manufacture of DUEXIS. In November 2011, the FDA approved the use of the sanofi-aventis Canada Inc. manufacturing site in Laval, Quebec to manufacture DUEXIS. In December 2011, Valeant acquired Dermik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S.

The first API in DUEXIS is ibuprofen in a direct compression blend called DC85, which is manufactured by BASF in Bishop, Texas. DC85 is a proprietary blend of ibuprofen and manufacturing capacity and batch quantities are currently sufficient to meet our forecasted commercial requirements. DC85 is manufactured in compliance with the FDA’s current good manufacturing practices regulations for pharmaceuticals, or cGMPs. The second API in DUEXIS is famotidine, which is available from a number of international suppliers. We purchase famotidine manufactured by Dr. Reddy’s in India. Dr. Reddy’s has been audited by the FDA and found to be compliant in all aspects of the product. Our personnel have also completed audits of each supplier location and did not identify any critical cGMP deficiencies. We currently receive both APIs in powder form and each is blended with a number of U.S. Pharmacopeia inactive ingredients. We purchase DUEXIS in final, packaged form exclusively from sanofi-aventis U.S. for our commercial requirements for DUEXIS in North America and certain countries and territories in Europe, including the European Union member states and Scandinavia, and South America.

**PENNSAID 2%**

In October 2014, in connection with the acquisition of the U.S. rights to PENNSAID 2% from Nuvo, we entered into an exclusive supply agreement with Nuvo. Under the supply agreement, Nuvo will manufacture and supply PENNSAID 2% to us at its manufacturing site in Varennes Québec, Canada. We have committed to a binding purchase order to Nuvo for delivery of PENNSAID 2%. In addition, at least 90 days prior to the first day of each calendar month during the term of the supply agreement, we are required to submit a binding written purchase order to Nuvo for PENNSAID 2% in minimum batch quantities. The initial term of our supply agreement is through December 31, 2022, but the agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party.

A key excipient used in PENNSAID as a penetration enhancer is dimethyl sulfoxide, or DMSO. Horizon and Nuvo rely on a sole proprietary form of DMSO for which we maintain a substantial safety stock. However, should this supply become inadequate, damaged, destroyed or unusable, we and Nuvo may not be able to qualify a second source.

**RAYOS/LODOTRA**

We rely on well-established third-party manufacturers for the manufacture of RAYOS/LODOTRA. In Europe, we retain quality responsibility for RAYOS/LODOTRA by controlling the final release of products. We purchase the primary active ingredients for RAYOS/LODOTRA from Tianjin Tianyao Pharmaceuticals Co., Ltd. in China and from Sanofi Chimie SA in France.
We have contracted with Jagotec for the production of RAYOS/LODOTRA tablets. Jagotec produces RAYOS/LODOTRA operating through its affiliate SkyePharma. The SkyePharma production site in Lyon, France, complies with cGMP requirements and has been audited by the FDA for the production of several sustained release tablets employing SkyePharma’s GeoMatrix technology. In August 2011, SkyePharma leased their entire pharmaceutical manufacturing business to Aenova, and Aenova is now a subcontractor for Jagotec for the manufacture of RAYOS/LODOTRA, with our consent. We consider Aenova an experienced and reliable contract manufacturer dedicated largely to advanced oral dosage forms. The commercial scale production of RAYOS/LODOTRA tablets was implemented prior to the launch of LODOTRA in Europe in 2009. Under our manufacturing and supply agreement, we were required to purchase RAYOS/LODOTRA exclusively from Jagotec through April 2014, after which we are able to purchase RAYOS/LODOTRA from other manufacturers if we choose.

Pursuant to a letter agreement between Jagotec and us, Jagotec agreed to allow us to give Bayer the right to manufacture, test and release quantities of RAYOS/LODOTRA in order to establish and maintain Bayer as a manufacturer of RAYOS/LODOTRA. Under certain circumstances, we may also purchase shortfall quantities of RAYOS/LODOTRA from Bayer to the extent Jagotec is unable to supply us. In March 2013, we entered into an agreement with Bayer to allow us to purchase quantities of RAYOS/LODOTRA for these purposes. After our manufacturing license from Jagotec becomes effective, we may also purchase quantities of RAYOS/LODOTRA from Bayer pursuant to our agreement with Bayer.

Analytical testing of RAYOS/LODOTRA is conducted by PHAST GmbH, a German provider of contract analytical services. The packaging of RAYOS/LODOTRA tablets is conducted by Temmler in Munich, Germany. Temmler was acquired by the Aenova Group in December 2012. Catalent Pharma Solutions in Schorndorf, Germany is registered as a second packaging site for Europe and U.S. supplies.

VIMOVO

In November 2013, in connection with our asset purchase agreement with AstraZeneca for VIMOVO, we entered into a transitional supply agreement with AstraZeneca pursuant to which AstraZeneca supplied VIMOVO to us for commercialization in the United States through December 31, 2014. We have completed transitioning the supply chain to third parties (including the packaging).

As part of this transition, in November 2013, we entered into a manufacturing agreement with Patheon, who was AstraZeneca’s contract bulk supply manufacturer of VIMOVO, pursuant to which Patheon will manufacture and package VIMOVO for us through December 31, 2019. Naproxen and esomeprazole magnesium trihydrate, the APIs in VIMOVO, are manufactured by Patheon into finished packaged tablets at its Cincinnati, Ohio manufacturing site. In March 2014, we entered into a manufacturing and supply agreement with Divis Laboratories Limited, or Divis, in India for the supply of naproxen. Also, in March 2014, we entered into a manufacturing and supply agreement with Minakem Holding SAS, or Minakem, in France for the supply of esomeprazole magnesium trihydrate.

Distribution

Finished tablets of DUEXIS, RAYOS and VIMOVO, vials of ACTIMMUNE, and bottles of PENNSAID 2% are shipped to central third-party logistics FDA-compliant warehouses for storage and distribution into the supply chain. Our third-party logistics providers specialize in integrated operations that include warehousing and transportation services that can be scaled and customized to our needs based on market conditions and the demands and delivery service requirements for our products and materials. Their services eliminate the need to build dedicated internal infrastructures that would be difficult to scale without significant capital investment. Our third-party logistics provider warehouses all finished product in controlled FDA-registered facilities. Incoming orders are prepared and shipped through an order entry system to ensure just in time delivery of the products.
Third-Party Coverage and Reimbursement

In both U.S. and foreign markets, our ability to commercialize our products successfully depends in significant part on the availability of coverage and adequate reimbursement to healthcare providers from third-party payers, including, in the United States, government payers such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Third-party payers are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. This is especially true in markets where over the counter and generic options exist. Even if coverage is made available by a third-party payer, the reimbursement rates paid for covered products might not be adequate. For example, third-party payers may use tiered coverage and may adversely affect demand for our products by not covering our products or by placing them in a more expensive formulary tier relative to competitive products (where patients have to pay relatively more out of pocket than for products in a lower tier). We cannot be certain that our products will be covered by third-party payers or that such coverage, where available, will be adequate, or that our products will successfully be placed on the list of drugs covered by particular health plan formularies. Many states have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. The industry competition to be included on such formularies and preferred drug lists often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payers may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other therapeutic alternative is available. In addition, because each third-party payer individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payer separately with no assurance that approval would be obtained, and we may need to conduct pharmaco-economic studies to demonstrate the cost effectiveness of our products for formulary coverage and reimbursement. Even with studies, our products may be considered less safe, less effective or less cost-effective than competitive products, and third-party payers may not provide coverage and adequate reimbursement for our products or our product candidates. These pricing and reimbursement pressures may create negative perceptions to any product price increases, or limit the amount we may be able to increase our product prices, which may adversely affect our product sales and results of operations. We may need to increasingly spend time and resources to ensure the prescriptions written for our products are filled as written, where appropriate.

Coverage policies, third-party reimbursement rates and product pricing regulation may change at any time. Even if favorable coverage and adequate reimbursement status is attained for one or more products that receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose extensive requirements upon the clinical development, pre-market approval, manufacture, labeling, marketing, promotion, pricing, import, export, storage and distribution of pharmaceutical products. These agencies and other regulatory agencies regulate research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, recordkeeping, advertising and promotion of
drugs. Failure to comply with applicable FDA or foreign regulatory agency requirements may result in Warning Letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations and biologics additionally under the Public Health Service Act. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA’s Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA or biologics license application, or BLA, as appropriate, after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities to assess compliance with cGMP regulations; and
- FDA review and approval of an NDA or BLA prior to any commercial marketing or sale of the product in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the U.S. IND are required in the EEA and other jurisdictions in which we may conduct clinical trials. Investigator-sponsored or investigator-initiated clinical trials are studies for which the investigator holds the IND, or equivalent regulatory filing in foreign jurisdictions, and is responsible for compliance with both the investigator and sponsor requirements under applicable law.

Clinical Trials. For purposes of NDA or BLA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

- Phase I Clinical Trials. Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism, and excretion, typically in healthy humans, but in some cases in patients.
• **Phase 2 Clinical Trials.** Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

• **Phase 3 Clinical Trials.** These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.

• **Phase 4 Clinical Trials.** The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a postmarketing commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase 4 clinical trials.

The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA, as appropriate. Applications also must contain extensive chemistry, manufacturing and control information. Applications must be accompanied by a significant user fee. Once the submission has been accepted for filing, the FDA’s goal is to review applications within 12 months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, eight months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA will typically conduct a pre-approval inspection of the manufacturer to ensure that the product can be reliably produced in compliance with cGMPs. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. The FDA may deny approval of an application by issuing a Complete Response Letter if the applicable regulatory criteria are not satisfied. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may occur with Risk Evaluation and Mitigation Strategies, or REMS, which limit the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

The **DUEXIS, PENNSAID 2%, RAYOS and VIMOVO NDAs** were submitted under Section 505(b)(2) of the FFDCA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely in part upon the FDA’s findings of safety and effectiveness for previously approved products, such as ibuprofen, famotidine and prednisone.

**DUEXIS, PENNSAID 2%, RAYOS and VIMOVO** have obtained, and any other products of ours approved by the FDA could obtain, three years of Hatch-Waxman marketing exclusivity, based upon our conducting or sponsoring new clinical investigations that are essential to approval of the respective NDA. Under this form of exclusivity, the FDA would be precluded from approving a generic drug application or, in some cases, another 505(b)(2) application for a drug product for the protected conditions of approval (for example, a product that incorporates the change or innovation represented by our product) for a period of three years, although the FDA
may accept and commence review of such applications at any time. However, this form of exclusivity would not prevent the FDA from approving an NDA that relies on its own clinical data to support the change or innovation. Further, if another company obtains approval for either product candidate for the same indication we are studying before we do, our approval could be blocked until the other company’s Hatch-Waxman marketing exclusivity expires.

**Other Regulatory Requirements.** Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review, payment of product and manufacturing establishment fees and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. Our products may be subject to REMS requirements that affect labeling, distribution or post market reporting. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Untitled Letters or Warning Letters that could cause us or our third-party manufacturers to modify certain activities. A Form 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. In addition to Form 483 notices and Untitled Letters or Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA requires us to recall a drug from distribution or withdraw approval for that product.

The FDA closely regulates the post-approval marketing and promotion of pharmaceuticals, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet, including certain social media activities. Products may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the product, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental application, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters or “untitled letters”, corrective advertising and potential administrative, civil and criminal penalties, as well as damages, fines, withdrawal of regulatory approval, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to sell our products or operate our business and also adversely affect our financial results.

Physicians may, in their independent medical judgment, prescribe legally available pharmaceuticals for uses that are not described in the product’s labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers’ communications regarding off-label use. Additionally, a significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for off-label uses and other sales practices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the Food, Drug and Cosmetic Act, false claims laws, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement.
our promotional activities, including any promotional activities that a contracted sales force may perform on our behalf, fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business. Thus, we are only permitted to market ACTIMMUNE, DUEXIS, PENNSAID 2%, RAYOS and VIMOVO for their approved indications and we could be subject to enforcement actions under various statutes if we engage in any off-label marketing.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution, including a drug pedigree which tracks the distribution of prescription drugs. Further, under the recently enacted Drug Quality and Security Act, drug manufacturers are subject to a number of requirements, including, product identification, tracing and verification, among others, that are designed to improve the detection and removal of counterfeit, stolen, contaminated or otherwise potentially harmful drugs from the U.S. drug supply chain. These requirements will be phased in over several years and compliance with this new law will likely increase the costs of the manufacture and distribution of drug products, which could have an adverse effect on our financial condition.

Outside the United States, our partners’ ability to market a product is contingent upon obtaining marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from country to country.

In the EMA (which is comprised of the 27 Member States of the European Union, plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining an MA. There are three types of marketing authorizations:

- **the Community MA**, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

- **Decentralized Procedure (DCP) MAs** are available for products not falling within the mandatory scope of the Centralized Procedure. An identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Concerned Member States, or CMS, for their approval. If the CMS raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling or packaging proposed by the RMS, the product is subsequently granted a national MA in all of the selected Member States (i.e. in the RMS and the selected CMS). Where a product has already been authorized for marketing in a Member State of the EEA, this DCP approval can be recognized in other Member States through the Mutual Recognition Procedure, or MRP.

- **National Procedure MAs**, which are issued by a single competent authority of the Member States of the EEA and only covers their respective territory, are also available for products not falling within the
mandatory scope of the Centralized Procedure. Once a product has been authorized for marketing in a Member State of the EEA through the National Procedure, this National MA can also be recognized in other Member States through the MRP.

Under the procedures described above, before granting the MA, the EMA or the competent authority(ies) of the Member State(s) of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Under Regulation (EC) No 726/2004/EC and Directive 2001/83/EC (each as amended), the European Union has adopted a harmonized approach to data and marketing exclusivity (known as the 8 + 2 + 1 formula). The approach permits eight years of data exclusivity and 10 years of marketing exclusivity. An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies.

The data exclusivity period begins on the date of the product’s first MA in the European Union and prevents generics from relying on the marketing authorization holder’s pharmacological, toxicological, and clinical data for a period of eight years. After eight years, a generic product application may be submitted and generic companies may rely on the marketing authorization holder’s data. However, a generic cannot launch until two years later (or a total of 10 years after the first marketing authorization in the European Union of the innovator product), or three years later (or a total of 11 years after the first MA in the European Union of the innovator product) if the MA holder obtains marketing authorization for a new indication with significant clinical benefit within the eight-year data exclusivity period.

The holder of a Community MA or National MA is subject to various obligations under applicable EEA regulations, such as pharmacovigilance obligations, requiring it to, among other things, report and maintain detailed records of adverse reactions, and to submit periodic safety update reports to the competent authorities. The holder must also ensure that the manufacturing and batch release of its product is in compliance with the applicable requirements. The MA holder is further obligated to ensure that the advertising and promotion of its products complies with applicable laws, which can differ from Member State to Member State of the EEA.

Healthcare Fraud and Abuse Laws. As a pharmaceutical company, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients’ rights are and will be applicable to our business. We may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. For example, in the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws are potentially applicable to manufacturers of products regulated by the FDA, such as us, and pharmacies, hospitals, physicians and other potential purchasers of such products.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. Several courts
have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute may have been violated, and enforcement will depend on the relevant facts and circumstances. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute to state that a person or entity needs not have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or to have offered improper inducements to federal health care program beneficiaries to select a particular provider or supplier. The federal Anti-Kickback Statute is broad, and despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors. In addition, where such activities involve foreign government officials, they may also potentially be subject to the Foreign Corrupt Practices Act. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including our activities with physician customers and pharmacies, as well as our activities pursuant to partnerships with other companies and pursuant to contracts with contract research organizations, could be subject to challenge under one or more of such laws.

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. In addition, the ACA specified that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. The federal False Claims Act has been the basis for numerous enforcement actions and settlements by pharmaceutical and other healthcare companies in connection with various alleged financial relationships with customers. In addition, a number of pharmaceutical manufacturers have reached substantial financial settlements in connection with allegedly causing false claims to be submitted because of the companies’ marketing of products for unapproved, and thus non-reimbursable, uses. Certain marketing practices, including off-label promotion, may also violate false claims laws, as might violations of the federal physician self-referral laws, such as the Stark laws, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician’s family member has a financial interest and prohibit submission of a claim for reimbursement pursuant to a prohibited referral. The “qui tam” provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted similar fraud and abuse statutes or regulations, including, without limitation, false claims laws analogous to the False Claims Act, and laws analogous to the federal Anti-Kickback Statute, that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer, and there are also federal criminal false claims laws.

Separately, there are a number of other fraud and abuse laws that pharmaceutical manufacturers must be mindful of, particularly after a product candidate has been approved for marketing in the United States. For example, a federal criminal law enacted as part of, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. There are also federal civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly
presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, as well as federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

**Healthcare Privacy and Security Laws.** We may be subject to, or our marketing activities may be limited by, HIPAA, as amended by the Health Information Technology and Clinical Health Act and their respective implementing regulations, which established uniform standards for certain “covered entities” (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. Among other things, HIPAA’s privacy and security standards are directly applicable to “business associates” — independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. In addition to possible civil and criminal penalties for violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney’s fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

**“Sunshine” and Marketing Disclosure Laws.** There are an increasing number of federal and state “sunshine” laws that require pharmaceutical manufacturers to make reports to states on pricing and marketing information. Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, and make periodic public disclosures on sales and marketing activities, and prohibiting certain other sales and marketing practices. In addition, a similar recently implemented federal requirement requires manufacturers, including pharmaceutical manufacturers, to track and report to the federal government certain payments and other transfers of value made to physicians and other healthcare professionals and teaching hospitals and ownership or investment interests held by physicians and their immediate family members. The federal government began disclosing the reported information on a publicly available website in 2014. These laws may adversely affect our sales, marketing, and other activities with respect to our products in the United States by imposing administrative and compliance burdens on us. If we fail to track and report as required by these laws or otherwise comply with these laws, we could be subject to the penalty provisions of the pertinent state and federal authorities.

**Government Price Reporting.** For those marketed products which are covered in the United States by the Medicaid programs, we have various obligations, including government price reporting and rebate requirements, which generally require products be offered at substantial rebates/discounts to Medicaid and certain purchasers (including “covered entities” purchasing under the 340B Drug Discount Program). We are also required to discount such products to authorized users of the Federal Supply Schedule of the General Services Administration, under which additional laws and requirements apply. These programs require submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations, and the guidance governing such calculations is not always clear. Compliance with such requirements can require significant investment in personnel, systems and resources, but failure to properly calculate our prices, or offer required discounts or rebates could subject us to substantial penalties.

In General. Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities, in the United States, could be subject to challenge under one or more of such laws. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including significant civil and criminal penalties, damages, fines, imprisonment, exclusion from participation in U.S. federal or state healthcare programs, and the curtailment or restructuring of our operations. To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and
abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, sunshine, government price reporting, and fraud laws may prove costly.

Impact of Healthcare Reform on Coverage, Reimbursement, and Pricing. In the United States and other potentially significant markets for our products, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States and on country-specific and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

The U.S. and some foreign jurisdictions are considering or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including, most recently, the ACA. The ACA, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, and impose additional health policy reforms, any or all of which may affect our business. The ACA is likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Other legislative changes have also been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to 2% per fiscal year, starting in 2013, and the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Such laws, and others that may affect our business that have been recently enacted or may in the future be enacted, may result in additional reductions in Medicare and other healthcare funding. In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of drug products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Employees

As of December 31, 2014, we had approximately 535 full-time employees as a consolidated entity. Of our employees as of December 31, 2014, approximately 30 were engaged in development, regulatory and manufacturing activities, approximately 440 were engaged in sales and marketing and approximately 65 were engaged in administration, including business development, finance, information systems, facilities and human resources. None of our employees is subject to a collective bargaining agreement. We consider our employee relations to be satisfactory.
Available Information

We make available free of charge on or through our internet website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. We also regularly post copies of our press releases as well as copies of presentations and other updates about our business on our website. Our internet address is www.horizonpharma.com. The information contained in or that can be accessed through our website is not part of this report. Information is also available through the Securities and Exchange Commission’s website at www.sec.gov, or is available at the Securities and Exchange Commission’s Public Reference Room located at 100 F Street, NE, Washington, DC, 20549. Information on the operation of the Public Reference Room is available by calling the Securities and Exchange Commission at 800-SEC-0330.

Item 1A. Risk Factors

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors in its entirety, in addition to other information contained in this report as well as our other public filings with the Securities and Exchange Commission.

Risks Related to Our Business and Industry

Our ability to generate revenues from our products is subject to attaining significant market acceptance among physicians, patients and healthcare payers.

Our current products, and other product or product candidates that we may develop, acquire, or in-license, such as PENNSAID 2% which we began commercializing in January 2015, may not attain market acceptance among physicians, patients, healthcare payers or the medical community. In the U.S. market, we began marketing DUEXIS in December 2011. We began commercial sales of DUEXIS in December 2011, to a subset of rheumatologists in the fourth quarter of 2012 with the full launch to the majority of U.S. rheumatologists and key primary care physicians in late January 2013. VIMOVO was launched in the U.S. market in the fourth quarter of 2010 by AstraZeneca AB, or AstraZeneca, under its license from Pozen Inc., or Pozen. Following our acquisition of the U.S. rights to VIMOVO in November 2013, we began marketing VIMOVO in the first quarter of 2014. ACTIMMUNE was originally launched in the U.S. market in March 1991 by Genentech and in June 2012, Vidara Therapeutics International plc, or Vidara, acquired the intellectual property rights and certain assets related to the ACTIMMUNE product line. In September 2014, the businesses of Horizon Pharma, Inc. and Vidara were combined, and as a result we assumed the commercialization of ACTIMMUNE. In October 2014 we entered into an asset purchase agreement with Nuvo Research Inc. to acquire the U.S. rights to PENNSAID 2%, and we began commercializing PENNSAID 2% in the United States in January 2015. Outside the United States, LODOTRA has been sold in a limited number of countries and sales may not grow to expected levels, in part because we depend on our distribution partner, Mundipharma International Corporation Limited, or Mundipharma, for commercialization outside the United States. With respect to DUEXIS, we have only received marketing approval in the United Kingdom, or UK, thus far, and even if it is approved in other European countries, we do not expect the opportunity in Europe to be material to our business given the current state of the market in Europe for pain products and the revenue being generated by existing branded non-steroidal anti-inflammatory drugs, or NSAIDs, in Europe. There have been no sales of DUEXIS in the UK thus far. We believe that the degree of market acceptance and our ability to generate revenues from our products will depend on a number of factors, including:

- timing of market introduction of our products as well as competitive drugs;
- efficacy and safety of our products;
- continued projected growth of the arthritis, pain and inflammation markets;
With respect to DUEXIS and VIMOVO, studies indicate that physicians do not commonly co-prescribe gastrointestinal, or GI, protective agents to high-risk patients taking NSAIDs. We believe this is due in part to a lack of awareness among physicians prescribing NSAIDs of the risk of NSAID-induced upper GI ulcers, in addition to the inconvenience of prescribing two separate medications and patient compliance issues associated with multiple prescriptions. If physicians remain unaware of, or do not otherwise believe in, the benefits of combining GI protective agents with NSAIDs, our market opportunity for DUEXIS and VIMOVO will be limited. Some physicians may also be reluctant to prescribe DUEXIS or VIMOVO due to the inability to vary the dose of ibuprofen and naproxen, respectively, or if they believe treatment with NSAIDs or GI protective agents other than those contained in DUEXIS and VIMOVO, including those of our competitors, would be more effective for their patients. With respect to each of DUEXIS, PENNSAID 2%, RAYOS/LODOTRA and VIMOVO, their higher cost compared to the generic or branded forms of their active ingredients alone may limit adoption by physicians, patients and healthcare payers. With respect to ACTIMMUNE, while it is the only FDA-approved treatment for chronic granulomatous disease, or CGD, and severe, malignant osteopetrosis, or SMO, they are very rare conditions and, as a result, our ability to grow ACTIMMUNE sales will depend on our ability to further penetrate this limited market and obtain marketing approval for additional indications. If our current products or any other product that we may seek approval for, acquire or in-license fail to attain market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

Our current business plan is highly dependent upon our ability to successfully execute on our sales and marketing strategy for the commercialization of ACTIMMUNE, DUEXIS, PENNSAID 2%, RAYOS/LODOTRA and VIMOVO. If we are unable to successfully execute on our sales and marketing strategy, we may not be able to generate significant product revenues or execute on our business plan. Our strategy is to build a fully-integrated U.S.-focused biopharmaceutical company to successfully execute the commercialization of our products in the U.S. market. We may not be able to successfully commercialize ACTIMMUNE, DUEXIS, PENNSAID 2%, RAYOS or VIMOVO in the United States. Prior to our commercial launch of DUEXIS in the United States in December 2011, we did not have any experience commercializing pharmaceutical products on our own. LODOTRA was commercially launched in Europe by our exclusive distribution partners Merck Serono and Mundipharma. In order to commercialize any approved products, we
must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. Although we have expanded our sales force to approximately 375 sales representatives, consisting of 325 primary care sales representatives and 50 sales representatives in specialty and orphan diseases business areas, in connection with our recent acquisition of the U.S. rights to PENNSAID 2%, we currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market these products and any additional products we may acquire or in-license will be expensive and time-consuming. We also cannot be certain that we will be able to continue to successfully develop this capability.

As a result of the evolving role of various constituents in the prescription decision making process, we adjusted the profile of the sales representatives we hire from those with traditional pharmaceutical sales experience to those with successful business to business experience. For example, we have faced challenges due to pharmacists increasingly switching a patient’s intended prescription from DUEXIS and VIMOVO to a generic or over the counter brand of their active ingredients. We have faced similar challenges for RAYOS with respect to generic brands and could face similar challenges with respect to PENNSAID 2% due to the availability of generic versions of PENNSAID 1.5%. While we believe the profile of our representatives is better suited for this evolving environment, we cannot be certain that our representatives will be able to successfully protect DUEXIS, PENNSAID 2%, RAYOS and VIMOVO prescriptions or that we will be able to continue attracting and retaining sales representatives with our desired profile and skills. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain commercial personnel. To the extent we rely on additional third parties to commercialize any approved products, we may receive less revenues than if we commercialized these products ourselves. In addition, we may have little or no control over the sales efforts of any third parties involved in our commercialization efforts. In the event we are unable to successfully develop and maintain our own commercial organization or collaborate with a third-party sales and marketing organization, we would not be able to commercialize our product candidates and execute on our business plan.

Legislation enacted in most states in the United States allows or, in some instances mandates, that a pharmacist dispense an available generic equivalent when filling a prescription for a branded product, in the absence of specific instructions from the prescribing physician. Because our products do not currently have FDA-approved generic equivalents in the United States, we do not believe our products should be subject to mandatory generic substitution laws. However we understand that some pharmacies and payors may attempt to reduce costs by obtaining physician authorization to switch prescriptions for DUEXIS or VIMOVO to prescriptions for multiple generic products with similar active pharmaceutical ingredients. Accordingly, a key part of our commercial strategy is to encourage physicians to have their patients agree to prescriptions through PME. Through PME, physicians can have their uninsured or commercially insured patients’ prescriptions for our products shipped directly to the patient. Through the PME program, we provide financial assistance to reduce eligible patient’s out of pocket costs for prescriptions filled via a participating mail order pharmacy. Because the patient out of pocket cost for our products when dispensed through the PME program may be significantly lower than such costs when our products are dispensed outside of the PME program, prescriptions that are filled through our PME program are therefore less likely to be subject to the efforts of traditional pharmacies to switch a physician’s intended prescription of our products to a generic or over the counter brand. We expect that continued adoption of our PME program by physicians and patients will be important to our ability to gain market share for our products as pressure from healthcare payors and PBMs to use less expensive generic or over the counter brands instead of branded products increases. For example, two of the largest PBMs, which we estimate to currently control approximately 20% to 30% of prescriptions for DUEXIS and VIMOVO, placed DUEXIS and VIMOVO on their exclusion lists beginning in 2015. Additional healthcare plans, including those that contract with these PBMs but use different formularies, may also choose to exclude our products from their formularies or restrict coverage to situations where a generic or over-the-counter product has been tried first. To the extent we are unable to successfully encourage physicians to direct prescriptions currently filled through traditional pharmacies, including those associated with/controlled by these PBMs, to our PME program, we may experience a significant decline in DUEXIS and VIMOVO prescriptions as a result of formulary exclusions. Our ability to increase adoption of our PME program will depend on physician and patient awareness and comfort.
with the program, and we have limited ability to influence whether physicians use our PME program to prescribe our products or whether patients will agree
to receive their products through the PME program. In addition, the PME program is only available to patients with commercial insurance or who are
uninsured, and is not available to federal health care program (such as Medicare and Medicaid) beneficiaries. If we are unable to increase adoption of our
PME program for filling prescriptions of our products, our ability to maintain or increase prescriptions for our products will be impaired. In addition, we
depend on a limited number of PME pharmacies to fulfill patient prescriptions under the PME program. If these PME pharmacies are unable to process and
fulfill the volume of patient prescriptions directed to them under the PME program, our ability to maintain or increase prescriptions for our products will be
impaired. The commercialization of our products and our operating results could be affected should any of the PME pharmacies choose not to continue
participation in our PME program or by any adverse events at any of those PME pharmacies.

If we are unable to successfully implement our commercial plans and drive adoption by patients and physicians of any approved products through our
sales, marketing and commercialization efforts, or if our partners fail to successfully commercialize our products, then we will not be able to generate
sustainable revenues from product sales which will have a material adverse effect on our business and prospects.

Our future prospects are highly dependent on the success of our current products, and we may not be able to successfully commercialize these
products. Failure to do so would adversely impact our financial condition and prospects.

A substantial majority of our resources are focused on the commercialization of our current products. Our ability to generate significant product
revenues and to achieve commercial success in the near-term will initially depend almost entirely on our ability to successfully commercialize these products
in the United States. DUEXIS has been approved for marketing in the UK but is not yet approved in any other countries in Europe and therefore, unless we
obtain regulatory approval in other countries, DUEXIS may not be commercialized to any significant extent outside of the United States. Even if DUEXIS is
approved in other European countries, we do not expect the opportunity in Europe to be material to our business given the current state of the market in
Europe for pain products and the revenue being generated by existing branded NSAIDs in Europe. Following our acquisition of the U.S. rights to VIMOVO in
November 2013 and PENNSAID 2% in October 2014, our strategy has included bringing both products’ pricing in-line with DUEXIS, thereby significantly
increasing the value we realize per prescription, and also increasing sales and marketing support to drive growth in prescriptions. We cannot guarantee that
this strategy will continue to be effective generally, due to negative reactions to price increases or otherwise. Our strategy for RAYOS is to solely focus on the
rheumatology indications approved for RAYOS where our Phase 3 clinical trial data supports our commercial plans. We initially launched RAYOS in the
United States to a subset of rheumatologists in the fourth quarter of 2012, and the full launch to the majority of U.S. rheumatologists and key primary care
physicians occurred in late January 2013. Our strategy with respect to ACTIMMUNE includes pricing increases, pursuing label expansion for additional
indications, such as Friedreich’s ataxia, or FA, and possible expansions of our sales force, but we cannot be certain that our pricing strategy will not result in
downward pressure on sales or that we will be able to successfully complete clinical trials and obtain regulatory approvals in additional indications.
Although LODOTRA is approved for marketing in more than 35 countries outside the United States, to date it has only been marketed in a limited number of
countries. While we anticipate that LODOTRA will be marketed in additional countries as our distribution partner, Mundipharma, formulates its
reimbursement strategy, the ability to market LODOTRA in additional countries will depend on Mundipharma’s ability to obtain reimbursement approvals in additional indications.
Even if we obtain additional marketing and reimbursement approvals, our product revenues in Europe are entirely dependent upon the
marketing efforts of our exclusive distribution partner, over which we have no control. Before we can market and sell these products in a particular
jurisdiction, we need to obtain necessary regulatory approvals (from the FDA in the United States and from similar foreign regulatory agencies in other
jurisdictions) and in some jurisdictions, reimbursement authorization. There are no guarantees that we or our commercialization partners will obtain any
additional regulatory approvals for our products. Even if we or our
commercialization partners obtain additional regulatory approvals, we may never generate significant revenues from any commercial sales of our products. If we fail to successfully commercialize our current and future products, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be adversely affected.

We are solely dependent on Mundipharma to commercialize LODOTRA in Europe and certain Asian, Latin American, Middle Eastern, African and other countries. Failure of Mundipharma or any other third parties to successfully commercialize our products and product candidates in the applicable jurisdictions could have a material adverse effect on our business.

We rely on Mundipharma for commercialization of LODOTRA in various European countries and certain Asian, Latin American, Middle Eastern, African and other countries. We have limited contractual rights to force Mundipharma to invest significantly in commercialization of LODOTRA in its markets. In the event that Mundipharma or any other third party with any future commercialization rights to any of our products or product candidates fails to adequately commercialize those products or product candidates because it lacks adequate financial or other resources, decides to focus on other initiatives or otherwise, our ability to successfully commercialize our products or product candidates in the applicable jurisdictions would be limited, which would adversely affect our business, financial condition, results of operations and prospects. We have had disagreements with Mundipharma under our European agreements and may continue to have disagreements, which could harm commercialization of LODOTRA in Europe or result in the termination of our agreements with Mundipharma. We also rely on Mundipharma’s ability to obtain regulatory approval for LODOTRA in certain Asian, Latin American, Middle Eastern, African and other countries. In addition, our agreements with Mundipharma may be terminated by either party in the event of a bankruptcy of the other party or upon an uncured material breach by the other party. If Mundipharma terminated its agreements with us, we may not be able to secure an alternative distributor in the applicable territory on a timely basis or at all, in which case our ability to generate revenues from the sale of LODOTRA would be materially harmed.

Our products are subject to extensive regulation, and we may not obtain additional regulatory approvals for our products.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution and other possible activities relating to our products and our product candidates are, and will be, subject to extensive regulation by the FDA and other regulatory agencies. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions.

To market any drugs outside of the United States, we and current or future collaborators must comply with numerous and varying regulatory and compliance related requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement and pricing approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Applications for regulatory approval, including a marketing authorization application for marketing new drugs in Europe, must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate. The number and types of preclinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the
time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical trials. Regulatory authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem a product candidate to be adequately safe and effective;
- may not find the data from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;
- may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than we do;
- may not approve the manufacturing processes or facilities associated with our product candidates;
- may conclude that we have not sufficiently demonstrated long-term stability of the formulation for which we are seeking marketing approval;
- may change approval policies (including with respect to our product candidates’ class of drugs) or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Even if we believe that data collected from our preclinical studies, CMC studies and clinical trials of our product candidates are promising and that our information and procedures regarding CMC are sufficient, our data may not be sufficient to support marketing approval by regulatory authorities, or regulatory interpretation of these data and procedures may be unfavorable. Even if approved, product candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed, restricted distribution methods or other limitations. Our business and reputation may be harmed by any failure or significant delay in obtaining regulatory approval for the sale of any of our product candidates. We cannot predict when or whether regulatory approval will be obtained for any product candidate we develop.

While we anticipate that LODOTRA will be marketed in additional countries as Mundipharma formulates its reimbursement strategy, the ability to market LODOTRA in additional countries will depend on Mundipharma’s ability to obtain regulatory and reimbursement approvals in these countries. Similarly, our ability to market DUEXIS outside of the United States will depend on obtaining regulatory and reimbursement approval in any country where DUEXIS may be marketed. However, certain countries have a very difficult reimbursement environment and we may not obtain reimbursement approval in all countries where DUEXIS may be marketed, or we may obtain reimbursement approval at a level that would make marketing DUEXIS in certain countries not viable.

Our limited history of commercial operations makes evaluating our business and future prospects difficult, and may increase the risk of any investment in our ordinary shares.

Following our acquisition of Vidara in September 2014 and our acquisition of the U.S. rights to PENNSAID 2% from Nuvo in October 2014, we have five products approved in the United States, one product with broad approval for commercial sale in Europe, and another product approved only for commercial sale in the UK thus far. RAYOS/LODOTRA has been approved in the United States and over 37 other countries, including Australia, Columbia and select countries within Europe and Asia. However, we have a limited history of marketing LODOTRA through our distribution partners, and LODOTRA is not yet marketed in all of the countries where it has been approved. We began the commercial sale of DUEXIS in the United States in November 2011, the commercial sale of RAYOS in the United States in the fourth quarter of 2012, the commercial sale of VIMOVO in the United States in the first quarter of 2014 and the commercial sale of ACTIMMUNE as a combined company with Vidara in September 2014. We began commercializing PENNSAID 2% in the United States in
January 2015. We face considerable risks and difficulties as a company with limited commercial operating history, particularly as a global consolidated entity with operating subsidiaries that also have limited operating histories. If we do not successfully address these risks, our business, prospects, operating results and financial condition will be materially and adversely harmed. Our limited commercial operating history, including our limited history commercializing PENNSAID 2% and VIMOVO and, as a combined company, ACTIMMUNE, makes it particularly difficult for us to predict our future operating results and appropriately budget for our expenses. In the event that actual results differ from our estimates or we adjust our estimates in future periods, our operating results and financial position could be materially affected. For example, we may underestimate the resources we will require to successfully integrate our commercial organization with Vidant’s or to commercialize VIMOVO, ACTIMMUNE and PENNSAID 2% within our organization or not realize the benefits we expect to derive from our recent acquisitions.

We have U.S. rights to ACTIMMUNE, PENNSAID 2% and VIMOVO but have no control over the activities of Boehringer Ingelheim to commercialize ACTIMMUNE outside the United States, Canada and Japan, AstraZeneca to commercialize VIMOVO outside of the United States or Nuvo or its licensees to commercialize PENNSAID 2% outside the United States, which could adversely impact commercialization of ACTIMMUNE, PENNSAID 2% and VIMOVO in the United States.

AstraZeneca has retained its existing rights to VIMOVO in territories outside of the United States, including the right to use the VIMOVO name and related trademark. Similarly, Nuvo has retained its rights to PENNSAID 2% in territories outside of the United States and has announced its intention to seek commercialization partners outside the United States. We have little or no control over AstraZeneca’s activities with respect to VIMOVO outside of the United States or over Nuvo’s or its future commercial partners activities with respect to PENNSAID 2% outside of the United States, even though those activities could impact our ability to successfully commercialize PENNSAID 2% and VIMOVO in the United States. For example, Nuvo or its assignees or AstraZeneca or its assignees can make statements or use promotional materials with respect to PENNSAID 2% or VIMOVO, respectively, outside of the United States that are inconsistent with our positioning of the products in the United States, and could sell PENNSAID 2% or VIMOVO, respectively, in foreign countries, including Canada, at prices that are dramatically lower than the prices we charge in the United States. These activities and decisions, while occurring outside of the United States, could harm our commercialization strategy in the United States, in particular because AstraZeneca is continuing to market VIMOVO outside the United States under the same VIMOVO brand name that we are using in the United States. In addition, product recalls or safety issues with PENNSAID 2% or VIMOVO outside the United States, even if not related to the commercial product we sell in the United States, could result in serious damage to the brand in the United States and impair our ability to successfully market PENNSAID 2% and VIMOVO. We also rely on Nuvo and AstraZeneca or its assignees to provide us with timely and accurate safety information regarding the use of PENNSAID 2% or VIMOVO, respectively, outside of the United States, as we have or will have limited access to this information ourselves.

We rely on third parties to manufacture commercial supplies of all of our products, and we currently intend to rely on third parties to manufacture commercial supplies of any other approved products. The commercialization of any of our products could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.

The facilities used by our third-party manufacturers to manufacture our products and product candidates must be approved by the applicable regulatory authorities. We do not control the manufacturing processes of third-party manufacturers and are currently completely dependent on our third-party manufacturing partners sanofi-aventis U.S. LLC, or sanofi-aventis U.S., operating through Valeant Pharmaceuticals International, Inc., or Valeant, its manufacturing partner located in Laval, Canada for production of DUEXIS, and Jagotec AG, or Jagotec, a wholly-owned subsidiary of SkyePharma PLC, located in Lyon, France, for production of RAYOS/LODOTRA. In August 2011, SkyePharma leased their entire pharmaceutical manufacturing business to Aenova France SAS, or Aenova. As such, Aenova is now a subcontractor for Jagotec for the manufacture of RAYOS/
LODOTRA, with our consent. Sanofi Winthrop Industrie in France has been qualified as a backup manufacturer for DUEXIS. Bayer Pharma AG in Germany
has been qualified as a backup manufacturer for RAYOS/LODOTRA. In December 2011, Valeant acquired Dermik, a dermatology unit of sanofi-aventis U.S.,
which includes the Laval, Canada site. Although, Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing
agreement remains with sanofi-aventis U.S. We purchase the primary active ingredients for DUEXIS from BASF Corporation in Bishop, Texas and
Dr. Reddy’s in India, and the primary active ingredient for RAYOS/LODOTRA from Tianjin Tianyao Pharmaceuticals Co., Ltd. in China and Sanofi Chimie
in France.

In connection with our acquisition of the U.S. rights to VIMOVO, we have entered into a long-term master manufacturing services and product
agreement with Parthenon Pharmaceuticals Inc., or Parthenon, for the supply of finished VIMOVO product. We have entered into long-term supply agreements
with Divis Laboratories Limited and Minakem Holding SAS for the supply of the active pharmaceutical ingredients, or APIs, of VIMOVO. In addition, we are
required to obtain AstraZeneca’s consent prior to engaging any third-party manufacturers for esomeprazole, one of the APIs in VIMOVO, other than the third-
party manufacturer(s) used by AstraZeneca or its affiliates or licensees. To the extent such manufacturers are unwilling or unable to manufacture
esomeprazole for us on commercially-acceptable terms, we cannot guarantee that AstraZeneca would consent to our use of alternate sources of supply.

With respect to ACTIMMUNE, we rely on an exclusive supply agreement with Boehringer Ingelheim RCV GmbH & Co KG, or Boehringer Ingelheim,
for manufacturing and supply. However, Boehringer Ingelheim also manufactures interferon gamma 1-b to supply its own commercial needs in its licensed
territory, and this may lead to capacity allocation issues and supply constraints to us. Furthermore, we do not have a substitute supplier for ACTIMMUNE
and the process of identifying a substitute supplier and getting that supplier approved by the applicable regulatory authorities for manufacture and
packaging of ACTIMMUNE can be a lengthy and costly process. ACTIMMUNE is manufactured by starting with cells from working cell bank samples which
are derived from a master cell bank. We and Boehringer Ingelheim separately store multiple vials of the master cell bank. In the event of catastrophic loss at
our or Boehringer Ingelheim’s storage facility, it is possible that we could lose multiple cell banks and have the manufacturing capacity of ACTIMMUNE
severely impacted by the need to substitute or replace the cell banks.

With respect to PENNSAID 2%, we rely on an exclusive supply agreement with Nuvo for manufacturing and supply. If Nuvo licenses its rights to
PENNSAID 2% to commercialization partners outside of the United States, it is possible that Nuvo would also agree to manufacture and supply PENNSAID
2% for those partners. In that case, we would have no guarantee that fulfilling demand for PENNSAID 2% in territories outside the United States would impair
Nuvo’s ability to supply us with our requested quantities of PENNSAID 2% in the United States. In addition, while our supply agreement with Nuvo provides
for the qualification of additional manufacturing sites for PENNSAID 2%, we and Nuvo may not be successful in finding alternative manufacturers to supply
PENNSAID 2% or agreeing to commercially reasonable terms with alternate suppliers. A key excipient used in PENNSAID as a penetration enhancer is
dimethyl sulfoxide, or DMSO. Horizon and Nuvo rely on a sole proprietary form of DMSO for which we maintain a substantial safety stock. However, should
this supply become inadequate, damaged, destroyed or unusable, we and Nuvo may not be able to qualify a second source.

If any of our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory
authorities’ strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing
facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified
personnel. If the FDA or any other applicable regulatory authorities do not approve these facilities for the manufacture of our products or if they withdraw any
such approval in the future, or if our suppliers or third-party manufacturers decide they no longer want to supply our primary active ingredients or
manufacture our products, we may need to find alternative manufacturing facilities, which would
significantly impact our ability to develop, obtain regulatory approval for or market our products. To the extent any third-party manufacturers that we engage with respect to our products are different than those currently being used for commercial supply in the United States, the FDA will need to approve the facilities of those third-party manufacturers used in the manufacture of our products prior to our sale of any product using these facilities.

Although we have entered into supply agreements for the manufacture of our products, our manufacturers may not perform as agreed or may terminate their agreements with us. Under our manufacturing and supply agreement with sanofi-aventis U.S., operating through Valeant, either we or sanofi-aventis U.S. may terminate the agreement upon an uncured breach by the other party or without cause upon two years prior written notice, so long as such notice is given after the third anniversary of the first commercial sale of DUEXIS. Under our master manufacturing services and product agreement with Patheon for finished VIMOVO product, either we or Patheon may terminate the agreement for uncured material breach by the other party or upon the other party’s bankruptcy or insolvency, we may terminate the agreement if any regulatory authority takes any action or raises any objection that prevents us from commercializing the VIMOVO product and Patheon may terminate the agreement if we assign our rights or obligations under the agreement to a competitor of Patheon or to a party that, in the reasonable opinion of Patheon, is not a credit worthy substitute for us, or in certain other circumstances where we assign the agreement without Patheon’s consent. Our manufacturing agreement with Boehringer Ingelheim has a term that runs until July 31, 2020, but the agreement may be terminated earlier by either us or Boehringer Ingelheim for an uncured material breach by the other party or upon the other party’s bankruptcy or insolvency. Under our manufacturing and supply agreement with Jagotec, either we or Jagotec may terminate the agreement in the event of an insolvency, liquidation or bankruptcy of the other party or upon an uncured breach by the other party. While we have the right to receive a continuing supply of RAYOS/LODOTRA from Jagotec for a period of 24 months after termination, we would need to move our manufacturing to our alternate supplier of RAYOS/LODOTRA, Bayer Pharma AG, in such an event and we would have to qualify a new back-up manufacturer. The initial term of our supply agreement with Nuvo for PENNSAID 2% is through December 31, 2022, but the agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party.

In addition, we do not have the capability to package any of our products for distribution. Consequently, we have entered into an agreement with Temmler Werke GmbH, or Temmler, for packaging of RAYOS/LODOTRA in certain European countries and in the United States, as well as any additional countries as may be agreed to by the parties. At the end of 2012, Temmler was acquired by the Aenova Group. Valeant manufactures and supplies DUEXIS to us in final, packaged form for the United States as well as any additional countries as may be agreed to by the parties. Patheon supplies final, packaged VIMOVO product pursuant to the master manufacturing services and product agreement we executed in connection with our acquisition of the U.S. rights to VIMOVO. Boehringer Ingelheim supplies final, packaged ACTIMMUNE to us and Nuvo is obligated to supply final, packaged PENNSAID 2% to us, in each case under exclusive supply agreements.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in the drug products or in the manufacturing facilities in which its products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that issues relating to the manufacture of any of our products will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to commercialize our products in the United States or provide any product candidates to patients in clinical trials would be jeopardized.
Any delay or interruption in our ability to meet commercial demand for our products will result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for these products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our products or product candidates and could have a material adverse effect on our business, results of operations, financial condition and prospects.

We have experienced recent growth and have expanded the size of our organization substantially in connection with our acquisition of the U.S. rights to VIMOVO in November 2013, our acquisition of Vidara in September 2014 and our acquisition of the U.S. rights to PENNSAID 2% in October 2014, and we may experience difficulties in managing this growth as well as potential additional growth in connection with future product acquisitions or company acquisitions.

As of December 31, 2010, we employed approximately 40 full-time employees as a consolidated entity. In anticipation of the commercial launch of DUEXIS, we hired approximately 80 sales representatives during the period from September 2011 through October 2011. Recently, we further increased the size of our sales force in connection with our acquisition of PENNSAID 2% to a total of approximately 375 sales representatives. As of December 31, 2014 and 2013, we employed approximately 535 and 463 full-time employees, respectively, as a consolidated entity. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire in connection with the commercialization of our products, requiring us to hire and train new sales representatives. Our management, personnel, systems and facilities currently in place may not be adequate to support this recent and anticipated growth, and we may not be able to retain or recruit qualified personnel in the future due to competition for personnel among pharmaceutical businesses.

As our commercialization plans and strategies continue to develop, we will need to continue to recruit and train sales and marketing personnel and expect to need to expand the size of our employee base for managerial, operational, financial and other resources as a result of our recent acquisitions of Vidara and PENNSAID 2%. Our ability to manage any future growth effectively may require us to, among other things:

- continue to manage and expand the sales and marketing efforts for our existing products;
- enhance our operational, financial and management controls, reporting systems and procedures;
- expand our international resources;
- successfully identify, recruit, hire, train, maintain, motivate and integrate additional employees;
- establish and increase our access to commercial supplies of our products and product candidates;
- expand our facilities and equipment; and
- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators, distributors and other third parties.

In particular, the merger of the businesses of Horizon Pharma, Inc. and Vidara Therapeutic International plc is subject to numerous uncertainties and risks and will require significant efforts and expenditures. For example, we have transitioned Horizon Pharma, Inc. from a standalone public Delaware corporation to being part of a combined company organized in Ireland. This combination has resulted in many changes, including significant changes in the corporate business and legal entity structure, the integration of Vidara and its personnel with those of Horizon, and changes in systems. We are currently undertaking numerous complex transition activities, and we may encounter unexpected difficulties or incur unexpected costs, including:

- difficulties in achieving growth prospects from combining the business of Vidara with that of Horizon;
• difficulties in the integration of operations and systems;
• difficulties in the assimilation of employees and corporate cultures;
• challenges in preparing financial statements and reporting timely results at both a statutory level for multiple entities and jurisdictions and at a consolidated level for public reporting;
• challenges in keeping existing customers and obtaining new customers; and
• challenges in attracting and retaining key personnel.

If any of these factors impair our ability to integrate the operations of Horizon with those of Vidara successfully or on a timely basis, we may not be able to realize the business opportunities, growth prospects and anticipated tax synergies from combining the businesses. In addition, we may be required to spend additional time or money on integration that otherwise would be spent on the development and expansion of our business.

Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities and towards managing these growth and integration activities. Our future financial performance and our ability to execute on our business plan will depend, in part, on our ability to effectively manage any future growth and our failure to effectively manage growth could have a material adverse effect on our business, results of operations, financial condition and prospects.

If we are unable to effectively train and equip our sales force, our ability to successfully commercialize our products in the United States will be harmed.

As DUEXIS and RAYOS were not fully commercially launched in the United States until January 2012 and January 2013, respectively, and we did not begin commercializing VIMOVO and PENNSAID 2% in the United States until the first quarter of 2014 and 2015, respectively, the members of our sales force have limited experience promoting the products. In addition, while the members of our sales force promoting ACTIMMUNE were previously promoting the product prior to the merger of the Horizon and Vidara businesses, we have limited experience marketing ACTIMMUNE under Horizon’s commercial organization. As a result, we are required to expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians to prescribe and pharmacists to dispense our products. In addition, we must train our sales force to ensure that a consistent and appropriate message about our products is being delivered to our potential customers. Our sales representatives may also experience challenges promoting multiple products when they call on physicians and their office staff. This is particularly true with respect to DUEXIS, since VIMOVO is approved for similar indications and prescribed to similar patients, and prior to 2014 our sales representatives had previously been incentivized to increase DUEXIS market share at the expense of VIMOVO. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire, requiring us to train new sales representatives. As a result of the managed care environment and pharmacies switching patient’s prescriptions to a generic or over the counter brand, we have had to adjust the profile of the sales representatives we hire from the traditional pharmaceutical representative to a representative with business to business experience that is focused on the total office call in order to protect the prescription the physician has written and ensure the patient receives what their doctor ordered. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of our products and their proper administration and label indication, as well as our PME program, our efforts to successfully commercialize our products could be put in jeopardy, which could have a material adverse effect on our financial condition, share price and operations.

We face significant competition from other biotechnology and pharmaceutical companies, including those marketing generic products and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and international markets, including major multinational pharmaceutical companies,
biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors and we may have to find new ways to compete and may have to potentially merge with or acquire other businesses to stay competitive. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or in-licensing on an exclusive basis, products that are more effective and/or less costly than our products.

DUEXIS and VIMOVO face competition from Celebrex®, marketed by Pfizer, and several other branded NSAIDs. DUEXIS and VIMOVO also face significant competition from the separate use of NSAIDs for pain relief and GI protective medications to reduce the risk of NSAID-induced upper GI ulcers. Both NSAIDs and GI protective medications are available in generic form and may be less expensive to use separately than DUEXIS or VIMOVO. PENNSAID 2% faces competition from generic versions of PENNSAID 1.5% that are priced significantly less than the price we charge for PENNSAID 2% and Voltaren Gel, marketed by Endo Pharmaceuticals, which is the market leader in the topical NSAID category. Legislation enacted in most states in the United States allows or, in some instances mandates, that a pharmacist dispense an available generic equivalent when filling a prescription for a branded product, in the absence of specific instructions from the prescribing physician. Because pharmacists often have economic and other incentives to prescribe lower-cost generics, if physicians prescribe DUEXIS, PENNSAID 2% or VIMOVO, those prescriptions may not result in sales. If we are unsuccessful in convincing physicians to complete prescriptions through our PME program or otherwise provide prescribing instructions prohibiting the substitution of generic ibuprofen and famotidine separately as a substitution for DUEXIS or generic naproxen and branded Nexium® (esomeprazole) as a substitute for VIMOVO or generic PENNSAID 1.5% as a substitute for PENNSAID 2%, sales of DUEXIS, PENNSAID 2% and VIMOVO may suffer despite any success we may have in promoting DUEXIS, PENNSAID 2% or VIMOVO to physicians. In addition, other product candidates that contain ibuprofen and famotidine in combination or naproxen and esomeprazole in combination, while not currently known to us, may be developed and compete with DUEXIS or VIMOVO, respectively, in the future.

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an Abbreviated New Drug Application, or ANDA, with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. We subsequently filed patent infringement lawsuits against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., or collectively Par, relating to the ANDA and Par's intention to market a generic version of DUEXIS. On August 21, 2013, we entered into a settlement agreement, or the Par settlement agreement, and license agreement, or the Par license agreement, with Par relating to its patent infringement litigation. The Par settlement agreement provides for a full settlement and release by both us and Par of all claims that were or could have been asserted in the litigation and that arise out of the specific patent issues that were the subject of the litigation, including all resulting damages or other remedies.

Under the Par license agreement, we granted Par a non-exclusive license (that is only royalty-bearing in some circumstances), or the License, to manufacture and commercialize Par's generic version of DUEXIS in the United States after the generic entry date and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par's generic version of DUEXIS prior to the generic entry date. The License covers all patents owned or controlled by us during the term of the Par license agreement that would, absent the License, be infringed by the manufacture, use, sale, offer for sale, or importation of Par's generic version of DUEXIS in the United States. Unless terminated sooner pursuant to the terms of the Par license agreement, the License will continue until the last to expire of the licensed patents and/or applicable periods of regulatory exclusivity.

Under the Par license agreement, the generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of potential future third
party DUEXIS patent litigation, the entry of other third party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. Only in the event that Par enters the DUEXIS market due to the specified changes in DUEXIS market conditions will the License become royalty-bearing, with the royalty obligations ceasing upon the occurrence of one of the other events that would have allowed Par to enter the DUEXIS market.

Under the Par license agreement, we also agreed not to sue or assert any claim against Par for infringement of any patent or patent application owned or controlled by us during the term of the Par license agreement based on the manufacture, use, sale, offer for sale, or importation of Par’s generic version of DUEXIS in the United States.

The Par license agreement may be terminated by us if Par commits a material breach of the agreement that is not cured or curable within 30 days after we provide notice of the breach. We may also terminate the Par license agreement immediately if Par or any of its affiliates initiate certain challenges to the validity or enforceability of any of the licensed patents or their foreign equivalents. In addition, the Par license agreement will terminate automatically upon termination of the Par settlement agreement.

On July 15, 2013, we received a Paragraph IV Patent Certification from Watson Laboratories, Inc. — Florida, known as Actavis Laboratories FL, Inc., or Watson, advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA’s review of its filing. On August 26, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Watson, Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc., or collectively WLF, seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. We, together with Jagotec have granted WLF a covenant not to sue with respect to US Patent Nos. 6,677,326 and 8,168,218, respectively, and accordingly these patents have been dismissed from the lawsuit. The court held a claim construction hearing on October 16, 2014, and issued its opinion and order on claim construction on November 10, 2014, adopting our proposed construction of both of the disputed claim terms. The court has scheduled expert discovery in the WLF action to be completed by June 2, 2015, and has set the pretrial conference for September 10, 2015. The trial date will be set following the pretrial conference.

On September 12, 2013, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS containing up to 5 mg of prednisone. On October 22, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par seeking an injunction to prevent the approval of the ANDA. The lawsuit alleged that Par had infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. On November 20, 2013, we were notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, we entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.

On November 13, 2014, we received a Paragraph IV Patent Certification from Watson advising that Watson had filed an ANDA with the FDA for a generic version of PENNSAID 2%. Watson has not advised us as to the timing or status of the FDA’s review of its filing. On December 23, 2014, we filed suit in the United States District Court for the District of New Jersey against Watson seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that Watson has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 51.
8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID 2% prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Watson’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The court has not yet set a trial date for the Watson action.

On December 2, 2014, we received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,741,956 from Paddock advising that Paddock had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On January 9, 2015, we received from Paddock another Paragraph IV Patent Certification against newly Orange Book listed U.S. Patent No. 8,871,809. Paddock has not advised us as to the timing or status of the FDA’s review of its filing. On January 13, 2015 and January 14, 2015, we filed suit in the United States District Court for the District of New Jersey and the United States District Court for the District of Delaware, respectively, against Paddock seeking an injunction to prevent the approval of the ANDA. The lawsuits alleged that Paddock has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID 2% prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Paddock’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The courts have not yet set trial dates for the Paddock actions.

On or about December 19, 2014, we filed a Notice of Opposition to a European patent, EP 2611457, to Roberto Testi, et al., covering compositions and methods for treating FA with interferon gamma, e.g., ACTIMMUNE. In the European Union, the grant of a patent may be opposed by one or more private parties.

The VIMOVO cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, January 4, 2013, May 10, 2013, June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We understand the Dr. Reddy’s notice letters were dated March 11, 2011 and November 20, 2012; the Lupin notice letters were dated June 10, 2011 and March 12, 2014; the Mylan notice letter was dated May 16, 2013; and the Actavis notice letters were dated March 29, 2013 and November 5, 2013; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order and has set a pretrial schedule but has not yet set a trial date.

On February 2, 2015, we received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, and 8,871,809 from Taro
Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd., or collectively Taro, advising that Taro had filed an ANDA with the FDA for a generic version of PENNSAID 2%. Taro has not advised us as to the timing or status of the FDA's review of its filing. We are still in the process of evaluating the Paragraph IV Patent Certification, and it is anticipated we will file suit against Taro within the statutorily prescribed 45 day time limit.

If we are unsuccessful in any of the on-going patent litigations, we will likely face generic competition with respect to VIMOVO, PENNSAID 2% and/or RAYOS and our sales of VIMOVO, PENNSAID 2% and/or RAYOS will be substantially harmed.

ACTIMMUNE is the only drug currently approved by the FDA specifically for the treatment for CGD and SMO. While there are additional or alternative approaches used to treat patients with CGD and SMO, there are currently no products on the market that compete directly with ACTIMMUNE. The current clinical standard of care to treat CGD patients in the United States is the use of concomitant “triple prophylactic therapy” comprising ACTIMMUNE, an oral antibiotic agent and an oral antifungal agent. However, the FDA-approved labeling for ACTIMMUNE does not discuss this “triple prophylactic therapy,” and physicians may choose to prescribe one or both of the other modalities in the absence of ACTIMMUNE. Because of the immediate and life-threatening nature of SMO, the preferred treatment option for SMO is often to have the patient undergo a bone marrow transplant which, if successful, will likely obviate the need for further use of ACTIMMUNE in that patient. We are aware of a number of research programs investigating the potential of gene therapy as a possible cure for CGD. Additionally, other companies may be pursuing the development of products and treatments that target the same diseases and conditions which ACTIMMUNE is currently approved to treat. As a result, it is possible that our competitors may develop new drugs that manage CGD or SMO more effectively, cost less or possibly even cure CGD or SMO. In addition, U.S. healthcare legislation passed in March 2010 authorized the FDA to approve biological products, known as biosimilars, that are similar to or interchangeable with previously approved biological products, like ACTIMMUNE, based upon potentially abbreviated data packages. Biosimilars are likely to be sold at substantially lower prices than branded products because the biosimilar manufacturer would not have to recoup the research and development and marketing costs associated with the branded product. The development and commercialization of any competing drugs or the discovery of any new alternative treatment for CGD or SMO could have a material adverse effect on sales of ACTIMMUNE and its profitability.

The availability and price of our competitors’ products could limit the demand, and the price we are able to charge, for our products. We will not successfully execute on our business objectives if the market acceptance of our products is inhibited by price competition, if physicians are reluctant to switch from existing products to our products, or if physicians switch to other new products or choose to reserve our products for use in limited patient populations.

In addition, established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license and develop novel compounds that could make our products obsolete. Our ability to compete successfully with these companies and other potential competitors will depend largely on our ability to leverage our experience in clinical, regulatory and commercial development to:

• develop, acquire or in-license medicines that are superior to other products in the market;

• attract qualified clinical, regulatory, and sales and marketing personnel;

• obtain patent and/or other proprietary protection for our products and technologies;

• obtain required regulatory approvals; and

• successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new product candidates.

The inability to compete with existing products or subsequently introduced products would have a material adverse impact on our business, financial condition and prospects.
Our business operations may subject us to numerous commercial disputes, claims and/or lawsuits.

Operating in the pharmaceutical industry, particularly the commercialization of pharmaceutical products, involves numerous commercial relationships, complex contractual arrangements, uncertain intellectual property rights, potential product liability and other aspects that create heightened risks of disputes, claims and lawsuits. In particular, we may face claims related to the safety of our products, intellectual property matters, employment matters, tax matters, commercial disputes, competition, sales and marketing practices, environmental matters, personal injury, insurance coverage and acquisition or divestiture-related matters. Any commercial dispute, claim or lawsuit may divert our management’s attention away from our business, we may incur significant expenses in addressing or defending any commercial dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results.

We are currently in litigation with multiple generic drug manufacturers regarding intellectual property infringement. For example, we are currently involved in Hatch Waxman litigation with generic drug manufacturers related to RAYOS and VIMOVO. Litigation related to these disputes may be costly and time-consuming and could materially and adversely impact our financial position and results of operations if resolved against us.

Similarly, from time to time we are involved in disputes with distributors, PBMs and licensing partners regarding their and our rights and performance of obligations under contractual arrangements. For example, we previously entered into a rebate agreement with a PBM, pursuant to which we were required to pay certain rebates on certain of our products that were reimbursed by health plans contracting with the PBM with respect to their formularies. In 2014, we sent a notice alerting the PBM of certain material breaches by the PBM under the agreement and indicating that the agreement would automatically terminate if the material breaches were not cured within 30 days. Among other things, the breaches by the PBM involved repeated invoices that included claims for rebates which were not eligible for payment under the agreement. Following the 30-day period, during which the PBM did not take action to cure the breaches or formally respond to the notice, we sent another notice informing the PBM that the agreement was terminated as of the end of the 30-day period in accordance with its terms and we ceased paying further rebates under the agreement. On November 6, 2014, we received a letter from the PBM asserting that the breaches we alleged in our termination notice were not material breaches and therefore the agreement was not terminated and remains in effect. In addition, the PBM claimed that we owe $38.5 million in past price protection and utilization rebates related to VIMOVO and DUEXIS, in addition to further rebates on sales of VIMOVO and DUEXIS continuing after the date we believe the agreement was terminated. The substantial majority of these rebate claims relate to price protection rebates on VIMOVO which we believe are precluded under the agreement, particularly because VIMOVO was not covered under the agreement until after we had established an initial price for VIMOVO under a Horizon-owned National Drug Code, or NDC. Based upon the terms of the agreement and the PBM’s actions, we believe that the PBM’s claims in its November 6, 2014 letter are without merit and we intend to vigorously defend against them. However, we cannot predict the outcome of this dispute, including whether it will result in litigation. If we are unsuccessful in defending against the PBM’s claims, and in light of the significant number of health plans that contract with the PBM, we could be forced to make substantial payments to the PBM for past and/or future rebates, at least through 2014. While the stated term of the agreement was through 2015, even if the PBM successfully argued that we did not validly terminate the contract due to material breach, we do not expect that we would owe further rebates in 2015 based on certain actions of the PBM. We cannot guarantee, however, that the PBM would not attempt to make arguments to the contrary. We also believe that we may have claims for damages that we could assert against the PBM. In any event, resolving the dispute with the PBM or being subject to related litigation may be costly and time-consuming and could materially and adversely impact our financial position and results of operations if resolved against us.
A variety of risks associated with operating our business and marketing our products internationally could materially adversely affect our business.

In addition to our U.S. operations, we have operations in Ireland, Bermuda, Luxembourg, Switzerland and Germany. Moreover, LODOTRA is currently being marketed in a limited number of countries outside the United States, and Mundipharma is in the process of obtaining pricing and reimbursement approval for, and preparing to market, LODOTRA in other European countries, as well as in certain Asian, Latin American, Middle Eastern and African countries. Also, Grünenthal S.A. is in the registration process for the commercialization of DUEXIS in Latin America. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

- compliance with differing or unexpected regulatory requirements for our products;
- compliance with Irish laws and the maintenance of our Irish tax residency with respect to our overall corporate structure and administrative operations, including the need to generally hold meetings of our board of directors and make decisions in Ireland, which may make certain corporate actions more cumbersome, costly and time-consuming;
- compliance with Swiss laws with respect to our Horizon Pharma AG subsidiary, including laws requiring maintenance of cash in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities;
- difficulties in staffing and managing foreign operations;
- in certain circumstances, including with respect to the commercialization of LODOTRA in Europe and certain Asian, Latin American, Middle Eastern and African countries, and commercialization of DUEXIS in Latin America, increased dependence on the commercialization efforts and regulatory compliance of our distributors or strategic partners;
- compliance with German laws with respect to our Horizon Pharma GmbH subsidiary through which Horizon Pharma AG conducts most of its European operations;
- foreign government taxes, regulations and permit requirements;
- U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- anti-corruption laws, including the Foreign Corrupt Practices Act;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- changes in diplomatic and trade relationships; and
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.
These and other risks associated with our international operations may materially adversely affect our business, financial condition and results of operations.

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects would be limited.

A key element of our strategy is to develop, acquire or in-license and commercialize a portfolio of other products or product candidates in addition to our current products. Because we do not engage in proprietary drug discovery, the success of this strategy depends in large part upon the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire or in-license approved or clinically enabled product candidates for therapeutic indications that complement or augment our current products, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting, acquiring or licensing promising products or product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product or product candidate, potentially resulting in a diversion of our management’s time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable products or product candidates from third parties on terms acceptable to us, or unable to raise capital required to acquire or in-license new products, our business and prospects will be limited.

Moreover, any product candidate we identify, select and acquire or license may require additional, time-consuming development or regulatory efforts prior to commercial sale, including preclinical studies if applicable, and extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risk of failure that is inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives.

In addition, if we fail to successfully commercialize and further develop our products, there is a greater likelihood that we will fail to successfully develop a pipeline of other product candidates to follow our existing products or be able to acquire other products to expand our existing portfolio, and our business and prospects would be harmed.

Our November 2013 acquisition of the U.S. rights to VIMOVO, the September 2014 merger with Vidara and our October 2014 acquisition of the U.S. rights to PENNSAID 2%, and any other strategic transactions that we may pursue in the future could have a variety of negative consequences, and we may not realize the benefits of such transactions or attempts to engage in such transactions.

We acquired the U.S. rights to VIMOVO in November 2013, merged the businesses of Horizon Pharma, Inc. and Vidara in September 2014 and acquired the U.S. rights to PENNSAID 2% in October 2014, and from time to time, we may seek to engage in additional strategic transactions with third parties, such as acquisitions of companies or divisions of companies, asset purchases or in-licensing of products or product candidates or technologies that we believe will complement or augment our existing business. We may also consider a variety of other business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and other investments. Any such transaction may require us to incur non-recurring and other charges, increase our near and long-term expenditures, pose significant integration challenges, create additional tax, legal, accounting and operational complexities in our business, require additional expertise, result in dilution to our existing shareholders and disrupt our management and business, which could harm our operations and financial results. For example, in connection with our acquisition of the U.S. rights to VIMOVO, we assumed primary responsibility for the existing patent infringement litigation with respect to VIMOVO, and have also agreed to reimburse certain legal expenses of Pozen with respect to its continued involvement in such litigation, and we expect that this will result in substantial on-going expenses and
potential distractions to our management team. Moreover, we face significant competition in seeking appropriate strategic transaction opportunities and the negotiation process for any strategic transaction can be time-consuming and complex. In addition, we may not be successful in our efforts to engage in certain strategic transactions because our financial resources may be insufficient and/or third parties may not view our commercial and development capabilities as being adequate. We may not be able to expand our business or realize our strategic goals if we do not have sufficient funding or cannot borrow or raise additional capital. There is no assurance that following our acquisition of the U.S. rights to VIMOVO, the merger with Vidara, our acquisition of the U.S. rights to PENNSAID 2% or any other strategic transaction, we will achieve the anticipated revenues, net income or tax benefits that we believe to justify such transaction. In addition, any failures or delays in entering into strategic transactions anticipated by analysts or the investment community could result in a decline in our share price.

We may not be able to successfully maintain our current advantageous tax status and resulting tax rates, which could adversely affect our business and financial condition, results of operations and growth prospects.

We are incorporated in Ireland and maintain subsidiaries in multiple jurisdictions, including Ireland, the United States, Switzerland, Luxembourg, Germany and Bermuda. Prior to our Merger, Vidara was able to achieve a favorable tax rate through the performance of certain functions and ownership of certain assets in tax-efficient jurisdictions, including Ireland and Bermuda, together with intra-group service and transfer pricing agreements, each on an arm’s length basis. We are continuing a substantially similar structure and arrangements. Taxing authorities, such as the U.S. Internal Revenue Service, or IRS, actively audit and otherwise challenge these types of arrangements, and have done so in the pharmaceutical industry. We expect that these challenges will continue as a result of the recent increase in scrutiny and political attention on corporate tax structures. The IRS may challenge our structure and transfer pricing arrangements through an audit or lawsuit. Responding to or defending such a challenge could be expensive and consume time and other resources, and divert management’s time and focus from operating our business. We cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. If we are unsuccessful, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could require us to reduce our operating expenses, decrease efforts in support of our products or seek to raise additional funds, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The IRS may not agree with our conclusion that we should be treated as a foreign corporation for U.S. federal income tax purposes following the combination of the businesses of Horizon Pharma, Inc. and Vidara Therapeutics International plc.

Although Horizon Pharma plc is incorporated in Ireland, the IRS, may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal income tax purposes pursuant to Section 7874 of the Internal Revenue Code of 1986, as amended, or the Code. A corporation is generally considered a tax resident in the jurisdiction of its organization or incorporation for U.S. federal income tax purposes. Because Horizon Pharma plc, the parent company of our organization, is an Irish incorporated entity, it would generally be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 provides an exception pursuant to which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal income tax purposes.

Under Section 7874, and as a result of the fact that the former shareholders of Horizon owned (within the meaning of Section 7874) less than 80% (by both vote and value) of the combined entity’s stock immediately after the merger, we believe we qualify as a foreign corporation for U.S. federal income tax purposes following the merger. However, there can be no assurance that there will not exist in the future a subsequent change in the facts or in law which might cause us to be treated as a domestic corporation for U.S. federal income tax purposes, including with retroactive effect.
Further, there can be no assurance that the IRS will agree with the position that the ownership test was satisfied. There is limited guidance regarding the application of Section 7874 of the Code, including with respect to the provisions regarding the application of the ownership test. If we were unable to be treated as a foreign corporation for U.S. federal income tax purposes, one of our significant strategic reasons for completing the Vidara merger would be nullified and we may not be able to recoup the significant investment in completing the transaction.

Future changes to U.S. and non-U.S. tax laws could materially adversely affect us.

Under current law, we expect to be treated as a foreign corporation for U.S. federal income tax purposes following the Vidara merger. However, changes to the rules in Section 7874 of the Code or regulations promulgated thereunder or other guidance issued by the Treasury or the IRS could adversely affect our status as a foreign corporation for U.S. federal income tax purposes, and any such changes could have prospective or retroactive application to us or our shareholders. On May 20, 2014 Senator Carl Levin and Representative Sander M. Levin introduced The Stop Corporate Inversions Act of 2014 (the “bill”) in the Senate and House of Representatives, respectively. In its current form, the bill would treat us as a U.S. Corporation as a result of the former shareholders of Horizon Pharma, Inc. owning 50% or more of the combined entity’s stock immediately following the Vidara merger. If enacted, the bill would apply to taxable years ending after May 8, 2014 and does not contain an exception for transactions subject to a binding commitment on that date. Additionally, in September 2014, legislation was introduced in the U.S. Senate that seeks to address the practice of earnings stripping by companies that move their domicile overseas. Furthermore, the Department of the Treasury and the IRS provided notice in September 2014 that the agencies intend to issue regulations to reduce the tax benefits of certain inversion transactions.

In addition, the U.S. Congress, the Organization for Economic Co-operation and Development, and other government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations and there are several current legislative and administrative proposals that, if enacted, would substantially change the U.S. federal income tax system as it relates to the taxation of multinational corporations. One example is in the area of “base erosion and profit shifting,” where payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. As a result, the tax laws in the United States and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could materially and adversely affect us.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, sales and marketing and scientific and medical personnel, including our executive committee comprised of our Chairman, President and Chief Executive Officer, Timothy P. Walbert; our Executive Vice President and Chief Business Officer, Robert F. Carey; our Executive Vice President and Chief Financial Officer, Paul W. Hoelscher; our Executive Vice President, Corporate Secretary and Managing Director, Ireland, David Kelly; our Executive Vice President and Chief Commercial Officer, John J. Kody; our Executive Vice President, Corporate Development, Barry J. Moze; and our Executive Vice President, Research and Development and Chief Medical Officer, Jeffrey W. Sherman, M.D. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide incentive stock options and restricted stock units that vest over time. The value to employees of stock options and restricted stock units that vest over time will be significantly affected by movements in our share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, sales and marketing, regulatory affairs, clinical affairs, medical affairs and development teams may terminate their employment with
us on short notice. Although we have written employment arrangements with all of our employees, these employment arrangements generally provide for at-will employment, which means that our employees can leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior sales and marketing and scientific and medical personnel.

Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize products and product candidates will be limited.

We are, with respect to our current products, and will be, with respect to any other product or product candidate for which we obtain FDA approval or acquire or in-license, subject to ongoing FDA obligations and continued regulatory review, which may result in significant additional expense. Additionally, any other product candidate, if approved by the FDA, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we obtain for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. In addition, with respect to our currently FDA-approved products (and with respect to our product candidates, if approved), the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product are subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or cGMPs, good clinical practices, or GCPs, international conference on harmonization regulations, or ICH regulations, and good laboratory practices, or GLPs, which are regulations and guidelines enforced by the FDA for all of our products in clinical development, for any clinical trials that we conduct post-approval. In connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we assumed responsibility for completing an ongoing Pediatric Research Equity Act post-marketing requirement study in children 12 years to 16 years and 11 months of age with Juvenile RA for which the FDA recently granted an extension with a final report due date of December 2015.

In addition, the FDA closely regulates the marketing and promotion of drugs. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturers’ promotional communications. A significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for off-label uses and other sales practices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the Food, Drug and Cosmetic Act, false claims laws, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. If we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.
Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, Warning Letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions, the imposition of civil or criminal penalties, or exclusions.

If we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

Coverage and reimbursement may not be available, or reimbursement may be available at only limited levels, for our products, which could make it difficult for us to sell our products profitably or to successfully execute planned product price increases.

Market acceptance and sales of our products will depend in large part on global coverage and reimbursement policies and may be affected by future healthcare reform measures, both in the United States and other key international markets. Successful commercialization of our products will depend in part on the availability of governmental and third-party payer reimbursement for the cost of our products. Government health administration authorities, private health insurers and other organizations generally provide reimbursement for healthcare. In particular, in the United States, private health insurers and other third-party payers often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the United States, the European Union and other significant or potentially significant markets for our products and product candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general. These pressures may create negative reactions to any product price increases, or limit the amount by which we may be able to increase our product prices, which may adversely affect our product sales and results of operations.

Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Third-party payers may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. Moreover, a third-party payer’s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Additionally, one third-party payer’s decision to cover a particular drug product does not ensure that other payors will also provide coverage for the drug product, or will provide coverage at an adequate reimbursement rate. Even though we have contracts with some PBMs in the United States, that does not guarantee that they will perform in accordance with the contracts, nor does it preclude them from taking adverse actions against us, which could materially adversely affect our operating results. In addition, the existence of such PBM contracts does not guarantee coverage by such PBM’s contracted
health plans or adequate reimbursement to their respective providers for our products. For example, two significant PBMs placed DUEXIS and VIMOVO on their exclusion lists beginning in 2015, which will result in a loss of reimbursement for patients’ whose healthcare plans have adopted these PBM lists. Also, as noted above, we are currently in an ongoing contract and rebate dispute with a U.S. PBM involving VIMOVO and DUEXIS, the outcome of which we cannot at this time determine, and which has the potential to negatively impact our relationship with that PBM, which could affect their coverage and/or reimbursement treatment of our other products. Additional healthcare plan formularies may also exclude our products from reimbursement due to the actions of these PBMs, future price increases we may implement, our use of PME program or any other co-pay programs, or other reasons. If our strategies to mitigate formulary exclusions are not effective, these events may reduce the likelihood that physicians prescribe our products and increase the likelihood that prescriptions for our products are not filled.

Outside of the United States, the success of our products, including LODOTRA and, if widely approved, DUEXIS, will depend largely on obtaining and maintaining government coverage, because in many countries patients are unlikely to use prescription drugs that are not covered by their government healthcare programs. To date, LODOTRA is approved in over 35 countries outside the United States, and reimbursement for LODOTRA has been obtained in Germany, Italy, Sweden and Switzerland. Mundipharma is seeking coverage for LODOTRA in a number of countries and currently sells LODOTRA without coverage in a limited number of countries. Negotiating coverage and reimbursement with governmental authorities can delay commercialization by 12 months or more. Coverage and reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and we expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceutical products, which we believe has impacted the reimbursement rates and timing to launch for LODOTRA to date, and we expect these discounts to continue as countries attempt to manage healthcare expenditures, especially in light of current economic conditions. For example, legislation was recently enacted in Germany that will increase the rebate on prescription pharmaceuticals and likely lower the revenues from the sale of LODOTRA in Germany that we would otherwise receive. As a result of these pricing practices, it may become difficult to achieve profitability or expected rates of growth in revenue or results of operations. Any shortfalls in revenue could adversely affect our business, financial condition and results of operations.

In light of such policies and the uncertainty surrounding proposed regulations and changes in the coverage and reimbursement policies of governments and third-party payers, we cannot be sure that coverage and reimbursement will be available for DUEXIS or LODOTRA in any additional markets or for any other product candidates that we may develop. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. If coverage and reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products.

We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. There may be additional pressure by payers and healthcare providers to use generic drugs that contain the active ingredients found in DUEXIS, PENNSAID 2%, RAYOS/LODOTRA and VIMOVO or any other product candidates that we may develop, acquire or in-license. If we fail to successfully secure and maintain coverage and adequate reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and expected revenue and profitability which would have a material adverse effect on our business, results of operations, financial condition and prospects. We may also experience pressure from payers concerning certain promotional approaches that we may implement such as PME program or any other co-pay programs whereby we assist qualified patients with certain out-of-pocket expenditures for our product. In addition, pharmaceutical manufacturer co-pay initiatives are the subject of evolving interpretations of applicable regulatory requirements, and any change in the regulatory or enforcement
environment regarding such programs could impact our ability to offer such programs. If we are unsuccessful with our PME program or any other co-pay initiatives, we would be at a competitive disadvantage in terms of pricing versus preferred branded and generic competitors.

We are subject to federal, state and foreign healthcare laws and regulations and implementation or changes to such healthcare laws and regulations could adversely affect our business and results of operations.

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to regulate and to change the healthcare system in ways that could affect our ability to sell our products profitably. In the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to civil and/or criminal penalties, damages, fines, exclusion from federal health care programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management’s attention away from the operation of our business.

We expect that the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product. An expansion in the government’s role in the U.S. healthcare industry may cause general downward pressure on the prices of prescription drug products, lower reimbursements for providers using our products, reduce product utilization and adversely affect our business and results of operations. It is unclear whether and to what extent, if at all, other potential developments resulting from the federal healthcare reform legislation, such as an increase in the number of people with health insurance and an increased focus on preventive medicine, may provide us additional revenue to offset the annual excise tax (on certain drug product sales) enacted under the ACA, subject to limited exceptions. It is possible that the tax burden, if we are not excepted, would adversely affect our financial performance, which in turn could cause the price of our share to decline. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our current products and/or those for which we may receive regulatory approval in the future.

We are subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

In the United States, we are subject directly, or indirectly through our customers, to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, federal and state privacy and security laws, sunshine laws, government price reporting laws, and other fraud laws, as described in greater detail in the Government Regulation Section of this report. These laws may impact, among other things, our current and proposed sales, marketing and educational programs, as well as other possible relationships with customers, pharmacies, physicians, payers, and patients.

Compliance with these laws, including the development of a comprehensive compliance program, is difficult, costly and time consuming. Because of the breadth of these laws and the narrowness of available
statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. These risks may be increased where there are evolving interpretations of applicable regulatory requirements, such as those applicable to manufacturer co-pay initiatives. We are engaged in various business arrangements with current and potential customers, and we can give no assurance that such arrangements would not be subject to scrutiny under such laws, despite our efforts to properly structure such arrangements. Even if we structure our programs with the intent of compliance with such laws, there can be no certainty that we would not need to defend our business activities against enforcement or litigation.

We are unable to predict whether we could be subject to actions under any of these or other fraud and abuse laws, or the impact of such actions. If we are found to be in violation of, or to encourage or assist the violation by third parties of any of the laws described above or other applicable state and federal fraud and abuse laws, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, withdrawal of regulatory approval, imprisonment, exclusion from government healthcare reimbursement programs, contractual damages, reputational harm, diminished profits and future earnings, injunctions and other associated remedies, or private “qui tam” actions brought by individual whistleblowers in the name of the government, and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business.

Our products or any other product candidate that we develop may cause undesirable side effects or have other properties that could delay or prevent regulatory approval or commercialization, result in product re-labeling or withdrawal from the market or have a significant impact on customer demand.

Undesirable side effects caused by any product candidate that we develop could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, or cause us to evaluate the future of our development programs. In our two Phase 3 clinical trials with DUEXIS, the most commonly reported treatment-emergent adverse events were nausea, dyspepsia, diarrhea, constipation and upper respiratory tract infection. In Phase 3 endoscopic registration clinical trials with VIMOVO, the most commonly reported treatment-emergent adverse events were erosive gastritis, dyspepsia, gastritis, diarrhea, gastric ulcer, upper abdominal pain, nausea and upper respiratory tract infection. The most common side effects observed in pivotal trials for ACTIMMUNE were “flu-like” or constitutional symptoms such as fever, headache, chills, myalgia and fatigue. The most commonly reported treatment-emergent adverse events in the Phase 3 clinical trials with RAYOS/LODOTRA included flare in RA-related symptoms, abdominal pain, nasopharyngitis, headache, flushing, upper respiratory tract infection, back pain and weight gain. The most common adverse events reported in a Phase 2 clinical trial of PENNSAID 2% were application site reactions, such as dryness, exfoliation, erythema, pruritus, pain, induration, rash and scabbing.

In addition, the FDA or other regulatory authorities may require, or we may undertake, additional clinical trials to support the safety profile of our product candidates.

In addition, if we or others identify undesirable side effects caused by our products or any other product candidate that we may develop that receives marketing approval, or if there is a perception that the product is associated with undesirable side effects:

- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- regulatory authorities may withdraw their approval of the product or place restrictions on the way it is prescribed;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product or implement a risk evaluation and mitigation strategy; and
- we may be subject to increased exposure to product liability and/or personal injury claims.
If any of these events occurred with respect to our products, our ability to generate significant revenues from the sale of these products would be significantly harmed.

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or if they experience regulatory compliance issues, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have agreements with third-party contract research organizations, or CROs, to conduct our clinical programs, including those required for post-marketing commitments. We may also have the need to enter into other such agreements in the future if we were to develop other product candidates or conduct clinical trials in additional indications for our existing products. In connection with our planned Phase 3 study to evaluate ACTIMMUNE in the treatment of FA, we are working with an academic research organization, who is the Clinical Trials Coordination Center, part of the Center for Human Experimental Therapeutics, in the University of Rochester to conduct the FA Phase 3 study as well as collaborating with the Friedreich’s Ataxia Research Alliance, or FARA, and select investigators of FARA’s Collaborative Clinical Research Network in FA. We rely heavily on these parties for the execution of our clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol. We and our CROs are required to comply with current GCP or ICH regulations. The FDA enforces these GCP or ICH regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP or ICH regulations, the data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCP or ICH regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations, and may require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our products and product candidates. As a result, our results of operations and the commercial prospects for our products and product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition or prospects.

In addition, pursuant to a March 2011 letter agreement and in connection with our waiver of certain milestone payments, Mundipharma initiated a separate Phase 3 clinical trial for LODOTRA for the potential treatment of polymyalgia rheumatica, or PMR. We had limited control over the timing and implementation of the planned clinical trial and in February 2014, Mundipharma informed us that they had terminated the clinical trial.
primarily due to recruitment difficulties based on the inclusion criteria and as a result of the cessation of production of the comparator product Decortin® 1mg.

In addition, in connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we assumed responsibility for completing an ongoing Pediatric Research Equity Act post-marketing requirement study in children 12 years to 16 years and 11 months of age with Juvenile Idiopathic Arthritis for which the FDA recently granted an extension with a final report due date of December 2015. Although we are committed to carrying out these commitments, there are challenges in conducting studies in pediatric patients including availability of study sites, patients, and obtaining parental informed consent.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of potential product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical testing.

With respect to our planned Phase 3 clinical trial to evaluate ACTIMMUTE for the treatment of FA, and to the extent that we are required to conduct additional clinical development of ACTIMMUNE, DUEXIS, PENNSAID 2%, RAYOS/LODOTRA or VIMOVO or we conduct clinical development of earlier stage product candidates or for other additional indications for ACTIMMUNE or RAYOS/LODOTRA, we may experience delays in these clinical trials. We do not know whether any additional clinical trials will be initiated in the future, begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board or ethics committee approval at each site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial;
- adding new sites; or
- manufacturing sufficient quantities of product candidates for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians’ and patients’ perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely and expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our future clinical trials and while we have and intend to have agreements governing their committed activities, we will have limited influence over their actual performance.

We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have
established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, our collaborators, the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or if we terminate, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Business interruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. While we carry insurance for certain of these events and have implemented disaster management plans and contingencies, the occurrence of any of these business interruptions could seriously harm our business and financial condition and increase our costs and expenses. Following the closing of our acquisition of Vidara, we conduct or plan to conduct significant management operations at both our global headquarters located in Dublin, Ireland and our U.S. office located in Deerfield, Illinois. If our Dublin or Deerfield offices were affected by a natural or man-made disaster or other business interruption, our ability to manage our domestic and foreign operations could be impaired, which could materially and adversely affect our results of operations and financial condition. We currently rely, and intend to rely in the future, on third-party manufacturers and suppliers to produce our products and third-party logistics partners to ship our products. Our ability to obtain commercial supplies of our products could be disrupted and our results of operations and financial condition could be materially and adversely affected if the operations of these third-party suppliers or logistics partners were affected by a man-made or natural disaster or other business interruption. The ultimate impact of such events on us, our significant suppliers and our general infrastructure is unknown.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

We face an inherent risk of product liability as a result of the commercial sales of our products and the clinical testing of our product candidates. For example, we may be sued if any of our products or product candidates allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products or product candidates that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
• a diversion of management’s time and our resources;
• substantial monetary awards to trial participants or patients;
• product recalls, withdrawals or labeling, marketing or promotional restrictions;
• loss of revenue;
• exhaustion of any available insurance and our capital resources;
• the inability to commercialize our products or product candidates; and
• a decline in our share price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies and commercial product sales in the amount of $20 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the on-going commercialization of our current products in the United States, and/or the potential commercial launches of DUEXIS and LODOTRA in additional markets, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our business involves the use of hazardous materials, and we and our third-party manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturers’ activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and our manufacturers are subject to federal, state and local as well as foreign laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state, federal or foreign authorities may curtail the use of these materials and interrupt our business operations. We do not currently maintain hazardous materials insurance coverage. If we are subject to any liability as a result of our third-party manufacturers’ activities involving hazardous materials, our business and financial condition may be adversely affected. In the future we may seek to establish longer term third-party manufacturing arrangements, pursuant to which we would seek to obtain contractual indemnification protection from such third-party manufacturers potentially limiting this liability exposure.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion,
sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Risks Related to Our Financial Position and Capital Requirements

We have incurred significant operating losses since our inception, and have not yet achieved profitability.

We have a limited operating history and even less history operating as a combined organization following the Vidara merger. We have financed our operations primarily through equity and debt financings, including the issuance of convertible notes, and have incurred significant operating losses since our inception. We had net losses of $263.6 million, $149.0 million and $87.8 million for the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014, we had an accumulated deficit of $720.7 million. Our losses have resulted principally from costs incurred in our development activities for our products and product candidates, commercialization activities related to our product launches and costs associated with derivative liability accounting. Our prior losses, combined with possible future losses, have had and will continue to have an adverse effect on our shareholders’ deficit and working capital. While we anticipate that we will become profitable in the future, whether and when we achieve this will depend on the revenues we generate from the sale of our products being sufficient to cover our operating expenses, and we have not achieved profitability to date.

We have limited product revenues and other sources of revenues. Even if we achieve profitability in the future, we cannot be certain that we will sustain profitability, which would depress the market price of our ordinary shares and could cause our investors to lose all or a part of their investment.

Our ability to become profitable depends upon our ability to generate revenues from sales of our products. DUEXIS was approved by the FDA on April 23, 2011, and we began generating revenues from sales of DUEXIS in late 2011 following the commercial launch in the United States. LODOTRA is approved for marketing in over 35 countries outside the United States, and to date we have generated only limited revenues from sales of LODOTRA. RAYOS was approved by the FDA on July 26, 2012, and we began marketing it in the United States through our full field sales force in late January 2013. Following our November 2013 acquisition of the U.S. rights to VIMOVO, we began commercialization efforts in the United States in the first quarter of 2014. ACTIMMUNE was originally launched in the U.S. market in March 1991 by Genentech and in June 2012, Vidara acquired the intellectual property rights and certain assets related to the ACTIMMUNE product line. In September 2014, the businesses of Horizon Pharma plc and Vidara were combined, and as a result we assumed the commercialization of ACTIMMUNE. In October 2014 we acquired the U.S. rights to PENNSAID 2% and began commercializing PENNSAID 2% in the United States in January 2015. We may never be able to successfully commercialize our products or develop or commercialize other products in the United States, which we believe represents our most significant commercial opportunity. Our ability to generate future revenues depends heavily on our success in:

- continued commercialization of our existing products and any other product candidates for which we obtain approval;
- obtaining FDA approvals for additional indications for ACTIMMUNE;
- securing additional foreign regulatory approvals for LODOTRA and DUEXIS; and
- developing, acquiring or in-licensing and commercializing a portfolio of other product candidates in addition to our current products.
We may need to obtain additional financing to further develop our existing products, or to develop, acquire or in-license other products. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

- commercialize our existing products in the United States, including due to the substantial expansion of our sales force we completed in connection with our November 2013 acquisition of the U.S. rights to VIMOVO and the additional expansion of our sales force in connection with our acquisition of U.S. rights to PENNSAID 2%;
- complete the regulatory approval process, and any future required clinical development related thereto, for our products;
- potentially acquire or in-license additional complementary products or products that augment our current product portfolio; and
- conduct clinical trials with respect to ACTIMMUNE for FA and any other potential indications beyond GCD or SMO.

While we believe that our existing cash and cash equivalents at December 31, 2014 of $218.8 million will be sufficient to fund our operations to the point of generating continuous positive cash flow based on our current expectations of continued revenue growth, we may need to raise additional funds if we choose to expand our commercialization or development efforts more rapidly than we presently anticipate, if we develop, acquire or in-license additional products or acquire companies, or if our revenues do not meet expectations.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research and development initiatives, or delay, cut back or abandon our plans to grow the business through acquisition or in-licensing. We also could be required to:

- seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

On June 17, 2014, we entered into a credit agreement with a group of lenders to provide us with $300.0 million in financing through a five-year senior secured credit facility, or the Senior Secured Credit Facility. Funding of the Senior Secured Credit Facility occurred coincident with the closing of the merger with Vidara. While the credit agreement provides for an uncommitted accordion facility from which we may potentially finance future acquisitions, funding under the accordion facility is subject to the satisfaction of certain financial and other conditions that we may not be able to meet at the times we may desire to fund an acquisition opportunity. If we are otherwise unable to secure financing to support future acquisitions, our ability to execute on a key aspect of our overall growth strategy would be impaired.

Our Swiss subsidiary, Horizon Pharma AG, is subject to Swiss laws regarding overindebtedness that require Horizon Pharma AG to maintain assets in excess of its liabilities. As of December 31, 2014, Horizon Pharma AG was not overindebted. However, Horizon Pharma AG has previously been overindebted, including at
December 31, 2013. We will continue to monitor and review Horizon Pharma AG’s financial position and, as necessary, will address any overindebtedness, which could require us to have cash at Horizon Pharma AG in excess of its near-term operating needs and could affect our ability to have sufficient cash at our other subsidiaries to meet their near-term operating needs.

Any of the above events could significantly harm our business, financial condition and prospects and cause the price of our ordinary shares to decline.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish intellectual property rights to our product candidates.

We may seek additional capital through a combination of private and public equity offerings, debt financings, receivables or royalty financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing shareholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our shareholders. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase shares, which could also result in dilution of our existing shareholders’ ownership. The incurrence of additional indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. For example, our borrowings under the Senior Secured Credit Facility subject us to significant fixed payment obligations in the future as we become obligated to repay the debt, and the Senior Secured Credit Facility contains affirmative and negative covenants that restrict our ability to incur additional indebtedness, grant liens, make investments, engage in mergers or dispositions, prepay other indebtedness and issue dividends or other distributions. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

We generally have broad discretion in the use of our cash and may not use it effectively.

Our management has broad discretion in the application of our cash, and investors will be relying on the judgment of our management regarding the use of our cash. Our management may not apply our cash in ways that ultimately increase the value of any investment in our securities. We expect to use our existing cash to fund U.S. commercialization activities for our products, to potentially fund additional regulatory approvals of DUEXIS, ACTIMMUNE and RAYOS/LODOTRA, to potentially fund development life cycle management or manufacturing activities of ACTIMMUNE, RAYOS/LODOTRA and PENNSAID 2% for other indications and for working capital, capital expenditures and general corporate purposes. We may also invest our cash in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our shareholders. If we do not invest or apply our cash in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause the price of our ordinary shares to decline.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. In September 2014, the Merger transaction triggered an “ownership change” limitation and, as a result, we will be subject to annual limits on our ability to utilize net operating loss carryforwards of Horizon Pharma Holdings USA Inc. and its subsidiary. We estimate this will result in annual limits of $91.1 million, $84.0 million and $84.0 million in 2015, 2016 and 2017, respectively. The net operating loss carryforward limitation is cumulative such that any use of the carryforwards below the limitation in one year will result in a corresponding increase in the limitation for the subsequent tax year.
Following certain acquisitions of a U.S. corporation by a foreign corporation, Section 7874 of the Code limits the ability of the acquired U.S. corporation and its U.S. affiliates to utilize U.S. tax attributes such as net operating losses to offset U.S. taxable income resulting from certain transactions. Based on the limited guidance available, we expect this limitation is applicable following the Vidara merger. As a result, it is not currently expected that Horizon Pharma, Inc. or our other U.S. affiliates will be able to utilize their U.S. tax attributes to offset their U.S. taxable income, if any, resulting from certain taxable transactions following the Vidara merger. Notwithstanding this limitation, we expect that Horizon Pharma, Inc. will be able to fully utilize its U.S. net operating losses prior to their expiration. As a result of this limitation, however, it may take Horizon Pharma, Inc. longer to use its net operating losses. Moreover, contrary to these expectations, it is possible that the limitation under Section 7874 of the Code on the utilization of U.S. tax attributes could prevent Horizon Pharma, Inc. from fully utilizing its U.S. tax attributes prior to their expiration if Horizon Pharma plc does not generate taxable income consistent with its expectations.

Any limitation on our ability to use our net operating loss carryforwards will likely increase the taxes we would otherwise pay in future years if we were not subject to such limitations.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

As widely reported, global credit and financial markets have experienced extreme disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. While there has been some recent improvement in some of these financial metrics, there can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate again, or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon commercialization or development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At December 31, 2014, we had $218.8 million of cash and cash equivalents consisting of cash and money market funds. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since December 31, 2014, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of marketable securities owned by us.

Changes in accounting rules or policies may affect our financial position and results of operations.

U.S. generally accepted accounting principles and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. Changes in these rules or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations. In addition, our operation as an Irish company with multiple subsidiaries in different jurisdictions adds additional complexity to the application of U.S. generally accepted accounting principles and this complexity will be exacerbated further if we complete additional strategic transactions. Changes in the application of existing rules or guidance applicable to us or our wholly-owned subsidiaries could significantly affect our consolidated financial position and results of operations.
Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

In November 2013, Horizon Pharma, Inc. issued $150.0 million aggregate principal amount of 5.00% Convertible Senior Notes due 2018, or the Convertible Senior Notes, to investors pursuant to note purchase agreements with such investors, and we subsequently guaranteed this debt at our parent entity. As of December 31, 2014, $61.0 million of principal amount of the Convertible Senior Notes remained outstanding. We also substantially increased our overall indebtedness to finance the Vidara merger. On June 17, 2014, we entered into the Senior Secured Credit Facility and borrowed $300.0 million, which is due after a five-year period. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Convertible Senior Notes and our borrowings under the Senior Secured Credit Facility, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Covenants imposed by the Senior Secured Credit Facility restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected.

The Senior Secured Credit Facility provides for (i) a committed five-year $300.0 million term loan facility, the proceeds of which were used primarily to effect the Vidara merger and pay fees and expenses in connection therewith and are being used in part for general corporate purposes; (ii) an uncommitted accordion facility subject to the satisfaction of certain financial and other conditions; and (iii) one or more uncommitted refinancing loan facilities with respect to loans under the Senior Secured Credit Facility. The Senior Secured Credit Facility imposes various covenants that limit our ability and/or our restricted subsidiaries’ ability to, among other things:

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- issue redeemable preferred shares;
- pay dividends or distributions or redeem or repurchase capital stock;
- prepay, redeem or repurchase certain debt;
- make loans, investments, acquisitions (including acquisitions of exclusive licenses) and capital expenditures;
- enter into agreements that restrict distributions from our subsidiaries;
- sell assets and capital stock of our subsidiaries;
- enter into certain transactions with affiliates; and
- consolidate or merge with or into, or sell substantially all of our assets to, another person.

The covenants imposed by the Senior Secured Credit Facility and our obligations to service our outstanding debt:

- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;
- limit our ability to use our cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions or other general business purposes;
may require us to use a substantial portion of our cash flow from operations to make debt service payments;
limit our flexibility to plan for, or react to, changes in our business and industry;
place us at a competitive disadvantage compared to our less leveraged competitors; and
increase our vulnerability to the impact of adverse economic and industry conditions.

If we are unable to successfully manage the limitations and decreased flexibility on our business due to our significant debt obligations, we may not be able to capitalize on strategic opportunities or grow our business to the extent we would be able to without these limitations.

Our failure to comply with any of the covenants could result in a default under the credit agreement, which could permit the administrative agent to, or permit the required lenders to cause the administrative agent to, declare all or part of any outstanding loans to be immediately due and payable or to exercise any remedies provided to the administrative agent, including proceeding against the collateral granted to secure our obligations under the Senior Secured Credit Facility. An event of default under the Senior Secured Credit Facility could also lead to an event of default under the terms of our Convertible Senior Notes. Any such event of default or any exercise of rights and remedies by our creditors could seriously harm our business.

If intangible assets that we have recorded in connection with the acquisitions of the U.S. rights to VIMOVO and PENNSAID 2% and the Vidara merger become impaired, we could have to take significant charges against earnings.

In connection with the accounting for acquisitions of the U.S. rights to VIMOVO and PENNSAID 2% and the Vidara merger, we have recorded significant amounts of intangible assets. Under U.S. GAAP, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other indefinite-lived intangible assets has been impaired. Amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders' equity in future periods.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products in the United States or in other foreign countries. If this were to occur, early generic competition could be expected against our current products and other product candidates in development. There is no assurance that the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the APIs in DUEXIS, VIMOVO and RAYOS/LODOTRA have been on the market as separate products for many years, it is possible that these products have previously been used off-label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications.

Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated.

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of DUEXIS,
containing 800 mg of ibuprofen and 26.6 mg of famotidine. In March 2012, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par’s ANDA and/or prevent Par from selling a generic version of DUEXIS. In January 2013, we filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par’s ANDA and/or prevent Par from selling a generic version of DUEXIS.

On August 21, 2013, we entered into the Par settlement agreement and Par license agreement with Par relating to its patent infringement litigation. The Par settlement agreement provides for a full settlement and release by both us and Par of all claims that were or could have been asserted in the litigation and that arise out of the specific patent issues that were the subject of the litigation, including all resulting damages or other remedies.

Under the Par license agreement, we granted Par a non-exclusive license (that is only royalty-bearing in some circumstances) to manufacture and commercialize Par’s generic version of DUEXIS in the United States after the generic entry date and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par’s generic version of DUEXIS prior to the generic entry date or the License. The License covers all patents owned or controlled by us during the term of the Par license agreement that would, absent the License, be infringed by the manufacture, use, sale, offer for sale, or importation of Par’s generic version of DUEXIS in the United States. Unless terminated sooner pursuant to the terms of the Par license agreement, the License will continue until the last to expire of the licensed patents and/or applicable periods of regulatory exclusivity.

Under the Par license agreement, the generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of potential future third party DUEXIS patent litigation, the entry of other third party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. Only in the event that Par enters the DUEXIS market due to the specified changes in DUEXIS market conditions will the License become royalty-bearing, with the royalty obligations ceasing upon the occurrence of one of the other events that would have allowed Par to enter the DUEXIS market.

Under the Par license agreement, we also agreed not to sue or assert any claim against Par for infringement of any patent or patent application owned or controlled by us during the term of the Par license agreement based on the manufacture, use, sale, offer for sale, or importation of Par’s generic version of DUEXIS in the United States.

The Par license agreement may be terminated by us if Par commits a material breach of the agreement that is not cured or curable within 30 days after we provide notice of the breach. We may also terminate the Par license agreement immediately if Par or any of its affiliates initiate certain challenges to the validity or enforceability of any of the licensed patents or their foreign equivalents. In addition, the Par license agreement will terminate automatically upon termination of the Par settlement agreement.

On July 15, 2013, we received a Paragraph IV Patent Certification from Watson advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA’s review of its filing. On August 26, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against WLF seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124, and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg, and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. We, together with Jagotec have granted WLF a covenant not to sue with respect to US Patent Nos. 6,677,326 and 8,168,218, respectively, and
accordingly these patents have been dismissed from the lawsuit. The Court held a claim construction hearing on October 16, 2014, and issued its opinion and order on claim construction on November 10, 2014, adopting our proposed construction of both of the disputed claim terms. The court has scheduled expert discovery in the WLF action to be completed by June 2, 2015, and has set the pretrial conference for September 10, 2015. The trial date will be set following the pretrial conference.

On September 12, 2013, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. On October 22, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par seeking an injunction to prevent the approval of the ANDA. The lawsuit alleged that Par had infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. On November 20, 2013, we were notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, we entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.

On November 13, 2014, we received a Paragraph IV Patent Certification from Watson advising that Watson had filed an ANDA with the FDA for a generic version of PENNSAID 2%. Watson has not advised us as to the timing or status of the FDA’s review of its filing. On December 23, 2014, we filed suit in the United States District Court for the District of New Jersey against Watson seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that Watson has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Watson’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The court has not yet set a trial date for the Watson action.

On December 2, 2014, we received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,741,956 from Paddock advising that Paddock had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On January 9, 2015, we received from Paddock another Paragraph IV Patent Certification against newly Orange Book listed U.S. Patent No. 8,871,809. Paddock has not advised us as to the timing or status of the FDA’s review of its filing. On January 13, 2015 and January 14, 2015, we filed suits in the United States District Court for the District of New Jersey and the United States District Court for the District of Delaware, respectively, against Paddock seeking an injunction to prevent the approval of the ANDA. The lawsuits allege that Paddock has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID 2% prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Paddock’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The courts have not yet set trial dates for the Paddock actions.

Currently, patent litigation is pending in the United States District Court for the District of New Jersey against four generic companies intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the United States District Court for the District of New Jersey and have been consolidated for discovery purposes. They are collectively known as the VIMOVO cases, and involve the following sets of defendants: (i) Dr. Reddy’s; (ii) Lupin; (iii) Mylan; and (iv) Actavis. Patent litigation in the United States District Court for the District of New Jersey against a fifth generic company, Anchen, was dismissed on June 9, 2014 after Anchen recertified under Paragraph III. We understand that Dr. Reddy’s has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy’s is now able to
commercialize VIMOVO under AstraZeneca’s Nexium patent rights. The settlement agreement, however, has no effect on the Pozen VIMOVO patents, which are still the subject of patent litigations. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

The VIMOVO cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, January 4, 2013, May 10, 2013, June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We understand the Dr. Reddy’s notice letters were dated March 11, 2011 and November 20, 2012; the Lupin notice letter were dated June 10, 2011 and March 12, 2014; the Mylan notice letter was dated May 16, 2013; the Actavis notice letters were dated March 29, 2013 and November 5, 2013; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order and has set a pretrial schedule but has not yet set a trial date.

On or about December 19, 2014, we filed a Notice of Opposition to a European patent, EP 2611457, to Roberto Testi, et al., covering compositions and methods for treating FA with interferon gamma, e.g., ACTIMMUNE. In the European Union, the grant of a patent may be opposed by one or more private parties.

On February 2, 2015, we received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, and 8,871,809 from Taro, advising that Taro had filed an ANDA with the FDA for a generic version of PENNSAID 2%. Taro has not advised us as to the timing or status of the FDA’s review of its filing. We are still in the process of evaluating the Paragraph IV Patent Certification, and it is anticipated we will file suit against Taro within the statutorily prescribed 45 day time limit.

We intend to vigorously defend our intellectual property rights relating to DUEXIS, VIMOVO, ACTIMMUNE, PENNSAID 2% and RAYOS, but we cannot predict the outcome of the WLF matter related to RAYOS or the DRL cases, the Mylan cases, or the Watson cases related to VIMOVO, or the Watson and Paddock cases related to PENNSAID 2%. Any adverse outcome in these matters or any new generic challenges that may arise could result in one or more generic versions of DUEXIS, VIMOVO, ACTIMMUNE, PENNSAID 2% and/or RAYOS being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to increase sales of DUEXIS, VIMOVO, ACTIMMUNE, PENNSAID 2% and/or RAYOS and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to DUEXIS, VIMOVO, ACTIMMUNE, RAYOS/LODOTRA or PENNSAID 2% fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them and threaten our ability to commercialize our products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to our products or any other product candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-

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how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or U.S. PTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third-parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that still require the U.S. PTO to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, the Patient Protection and Affordable Care Act allows applicants seeking approval of biosimilar or interchangeable versions of biological products such as ACTIMMUNE to initiate a process for challenging some or all of the patents covering the innovator biological product used as the reference product. This process is complicated and could result in the limitation or loss of certain patent rights. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States and Canada. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving
patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the U.S. PTO. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our products and/or any other product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications, which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys’ fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, we could lose license rights that are important to our business.

We are a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. For example, we hold an exclusive license to SkyPharma AG’s proprietary technology and know-how covering the delayed release of corticosteroids relating to RAYOS/LODOTRA. If we fail to comply with our obligations under our agreement with SkyPharma or our other license agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license, including RAYOS/LODOTRA.

In connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we (i) received the benefit of a covenant not to sue under AstraZeneca’s patent portfolio with respect to Nexium (which shall automatically become a license under such patent portfolio if and when AstraZeneca reacquires control of such patent portfolio from Merck Sharp & Dohme Corp. and certain of its affiliates), (ii) were assigned AstraZeneca’s
amended and restated collaboration and license agreement for the United States with Pozen under which AstraZeneca has in-licensed exclusive rights under
certain of Pozen’s patents with respect to VIMOVO, and (iii) acquired AstraZeneca’s co-ownership rights with Pozen with respect to certain joint patents
covering VIMOVO, all for the commercialization of VIMOVO in the United States. If we fail to comply with our obligations under our agreements with
AstraZeneca or if we fail to comply with our obligations under our agreements with Pozen as we take over AstraZeneca’s agreements with Pozen, our rights to
commercialize VIMOVO in the United States may be adversely affected or terminated by AstraZeneca or Pozen.

We also license rights to patents, know-how and trademarks for ACTIMMUNE from Genentech, under an agreement that remains in effect for so long as
we continue to commercialize and sell ACTIMMUNE. However, Genentech may terminate the agreement upon our material default, if not cured within a
specified period of time. Genentech may also terminate the agreement in the event of our bankruptcy or insolvency. Upon such a termination of the
agreement, all intellectual property rights conveyed to us under the agreement, including the rights to the ACTIMMUNE trademark, revert to Genentech. If
we fail to comply with our obligations under this agreement, we could lose the ability to market and distribute ACTIMMUNE, which would have a material
adverse effect on our business, financial condition or results of operations.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and
unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file
infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our
licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover
the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or
interpreted narrowly and could put our patent applications at risk of not issuing.

There are numerous post grant review proceedings available at the US Patent Office (including inter partes review, post-grant review and ex-parte
reexamination) and similar proceedings in other countries of the world that could be initiated by a third party that could potentially negatively impact our
issued patents.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our
patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to
attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially
reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our
management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights,
particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our
confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of
hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a
material adverse effect on the price of our ordinary shares.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other
requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these
requirements.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the
patent. The U.S. PTO and various foreign governmental patent
agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees’ former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Risks Related to Ownership of our Ordinary Shares

We do not know whether an active, liquid and orderly trading market for our ordinary shares will be sustained or what the market price of our ordinary shares will be and as a result it may be difficult for you to sell your ordinary shares.

Although our ordinary shares are listed on The NASDAQ Global Market, an active trading market for our shares may never be sustained. Further, an inactive market may impair our ability to raise capital by selling our ordinary shares and may impair our ability to enter into strategic partnerships or acquire companies or products by using our ordinary shares as consideration.

The market price of our ordinary shares historically has been volatile and is likely to be highly volatile, and you could lose all or part of your investment.

The trading price of our ordinary shares has been highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this report, these factors include:

- our failure to successfully execute our commercialization strategy with respect to our approved products, particularly our commercialization of our products in the United States;
- actions or announcements by third party or government payors with respect to coverage and reimbursement of our products;
- disputes or other developments relating to intellectual property and other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products and product candidates;
- unanticipated serious safety concerns related to the use of our products;
- adverse regulatory decisions;
- changes in laws or regulations applicable to our business, products or product candidates, including but not limited to clinical trial requirements for approvals or tax laws;
• inability to comply with our debt covenants and to make payments as they become due;
• inability to obtain adequate commercial supply for any approved product or inability to do so at acceptable prices;
• developments concerning our commercial partners, including but not limited to those with our sources of manufacturing supply;
• our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
• adverse results or delays in clinical trials;
• our failure to successfully develop, acquire, and/or in-license additional product candidates or obtain approvals for additional indications for our existing product candidates;
• introduction of new products or services offered by us or our competitors;
• our inability to effectively manage our growth;
• overall performance of the equity markets and general political and economic conditions;
• failure to meet or exceed revenue and financial projections we may provide to the public;
• actual or anticipated variations in quarterly operating results;
• failure to meet or exceed the estimates and projections of the investment community;
• publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
• our inability to successfully enter new markets;
• the termination of a collaboration or the inability to establish additional collaborations;
• announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
• our inability to maintain an adequate rate of growth;
• ineffectiveness of our internal controls or our inability to otherwise comply with financial reporting requirements;
• adverse U.S. and foreign tax exposure;
• additions or departures of key management, commercial or regulatory personnel;
• issuances of debt or equity securities;
• significant lawsuits, including patent or shareholder litigation;
• changes in the market valuations of similar companies;
• sales of our ordinary shares by us or our shareholders in the future;
• trading volume of our ordinary shares;
• effects of natural or man-made catastrophic events or other business interruptions; and
• other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The NASDAQ Global Market and the stocks of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may adversely affect the market price of our ordinary shares, regardless of our actual operating performance.
We do not intend to pay dividends on our ordinary shares so any returns will be limited to the value of our shares. We have never declared or paid any cash dividends on our ordinary shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future, including due to limitations imposed by the Senior Secured Credit Facility. Any return to shareholders will therefore be limited to the increase, if any, of our share price.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In particular, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the NASDAQ Stock Market, Inc., or NASDAQ, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. These rules and regulations have substantially increased our legal and financial compliance costs and have made some activities more time-consuming and costly. These effects are exacerbated by our transition to an Irish company and the integration of Vidara’s business and operations into the historical business and operating structure of Horizon Pharma, Inc. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will continue to decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it more difficult and more expensive for us to obtain and maintain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. If we fail to comply with the continued listing requirements of NASDAQ, our ordinary shares could be delisted from The NASDAQ Global Market, which would adversely affect the liquidity of our ordinary shares and our ability to obtain future financing.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we are required to perform annual system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Our independent registered public accounting firm is also required to deliver a report on the effectiveness of our internal control over financial reporting. Our testing, or the testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 requires that we incur substantial expense and expend significant management efforts, particularly because of our Irish parent company structure and international operations. In particular, prior to the Vidara merger, Vidara and its affiliate entities were not subject to the requirements of the Sarbanes-Oxley Act. We intend to take appropriate measures to establish or implement an internal control environment at the former Vidara entities aimed at successfully adopting the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. However, it is possible that we may experience delays in implementing or be unable to implement the required internal controls over financial reporting and other disclosure controls and procedures. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, as well as retain and work with consultants with such knowledge. Moreover, if we are not able to comply with the requirements of Section 404 or if we or our independent registered public accounting firm identify deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our ordinary shares could decline and we could be subject to sanctions.
or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act and rules adopted by the SEC and by NASDAQ, would likely result in increased costs to us as we respond to their requirements.

Sales of a substantial number of our ordinary shares in the public market could cause our share price to decline.

If our existing shareholders sell, or indicate an intention to sell, substantial amounts of our ordinary shares in the public market, the trading price of our ordinary shares could decline. In addition, our ordinary shares that are either subject to outstanding options or reserved for future issuance under our employee benefit plans are or may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares could decline.

Certain holders of our ordinary shares are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. For example, we are subject to a registration rights agreement with certain holders of our ordinary shares prior to the Vidara merger. Pursuant to this agreement, we filed and are required to maintain a registration statement covering the resale of our ordinary shares held by these shareholders and in certain circumstances, these holders can require us to participate in an underwritten public offering of their ordinary shares. Any sales of securities by these shareholders or a public announcement of such sales could have a material adverse effect on the trading price of our ordinary shares.

Future sales and issuances of our ordinary shares, securities convertible into our ordinary shares or rights to purchase ordinary shares or convertible securities could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to decline.

Additional capital may be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. We may sell ordinary shares, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell ordinary shares, convertible securities or other equity securities in subsequent transactions, our existing shareholders may be materially diluted. New investors in such subsequent transactions could gain rights, preferences and privileges senior to those of holders of our ordinary shares. We also maintain equity incentive plans, including our 2014 Equity Incentive Plan, 2014 Non-Employee Equity Plan and 2014 Employee Share Purchase Plan, and intend to grant additional ordinary share awards under these and future plans, which will result in additional dilution to existing shareholders.

Irish law differs from the laws in effect in the United States and may afford less protection to holders of our securities.

It may not be possible to enforce court judgments obtained in the United States against us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of the U.S. federal or state securities laws or hear actions against us or those persons based on those laws. We have been advised that the U.S. currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state
court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.

As an Irish company, we are governed by the Irish Companies Acts, which differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our securities may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a jurisdiction of the United States.

**Provisions of our articles of association could delay or prevent a takeover of us by a third party.**

Our articles of association could delay, defer or prevent a third party from acquiring us, despite the possible benefit to our shareholders, or otherwise adversely affect the price of our ordinary shares. For example, our articles of association:

- permit our board of directors to issue one or more series of preferred shares with rights and preferences designated by our board;
- impose advance notice requirements for shareholder proposals and nominations of directors to be considered at shareholder meetings;
- stagger the terms of our board of directors into three classes; and
- require the approval of a supermajority of the voting power of the shares of our share capital entitled to vote generally in the election of directors for shareholders to amend or repeal our articles of association.

These provisions may discourage potential takeover attempts, discourage bids for our ordinary shares at a premium over the market price or adversely affect the market price of, and the voting and other rights of the holders of, our ordinary shares. These provisions could also discourage proxy contests and make it more difficult for you and other shareholders to elect directors other than the candidates nominated by our board.

**A transfer of our ordinary shares may be subject to Irish stamp duty.**

In certain circumstances, the transfer of shares in an Irish incorporated company will be subject to Irish stamp duty, which is a legal obligation of the buyer. This duty is currently charged at the rate of 1.0% of the price paid or the market value of the shares acquired, if higher. Because our ordinary shares are traded on a recognized stock exchange in the United States, an exemption of this stamp duty is available to transfers by shareholders who hold our ordinary shares beneficially through brokers which in turn hold those shares through the Depositary Trust Company, or DTC, to holders who also hold through DTC. However, a transfer by a record holder who holds our ordinary shares directly in his, her or its own name could be subject to this stamp duty. We, in our absolute discretion and insofar as the Companies Acts or any other applicable law permit, may, or may provide that a subsidiary of ours will, pay Irish stamp duty arising on a transfer of our ordinary shares on behalf of the transferee of such ordinary shares. If stamp duty resulting from the transfer of our ordinary shares which would otherwise be payable by the transferee is paid by us or any of our subsidiaries on behalf of the transferee, then in those circumstances, we will, on our behalf or on behalf of our subsidiary (as the case may be), be entitled to (i) seek reimbursement of the stamp duty from the transferee, (ii) set-off the stamp duty against any dividends payable to the transferee of those ordinary shares and (iii) claim a first and permanent lien on the ordinary shares on which stamp duty has been paid by us or our subsidiary for the amount of stamp duty paid. Our lien shall extend to all dividends paid on those ordinary shares.
If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our ordinary shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our shares or publish inaccurate or unfavorable research about our business, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our ordinary shares could decrease, which might cause our share price and trading volume to decline.

*We may become involved in securities class action litigation that could divert management’s attention and harm our business and could subject us to significant liabilities.*

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the equity securities of pharmaceutical companies. These broad market fluctuations may cause the market price of our ordinary shares to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Even if we are successful in defending against any such claims, litigation could result in substantial costs and may be a distraction to management, and may result in unfavorable results that could adversely impact our financial condition and prospects.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

We occupy approximately 10,300 square feet of office space in our headquarters in Dublin, Ireland under a lease that expires on November 4, 2029. We also occupy approximately 50,500 square feet of office space in Deerfield, Illinois under lease agreements that expire on June 30, 2018, approximately 5,000 square feet of office space in Mannheim, Germany under a lease that expires on December 31, 2016, approximately 3,200 square feet of office space in Reinach, Switzerland under a lease that expires on May 31, 2015 and approximately 6,200 square feet of office space in Roswell, Georgia under a lease that expires on October 31, 2018. We believe that our current facilities are adequate for our needs and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

**Item 3. Legal Proceedings**

On July 15, 2013, we received a Paragraph IV Patent Certification from Watson Laboratories, Inc.—Florida, known as Actavis Laboratories FL, Inc., or Watson, advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA’s review of its filing. On August 26, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Watson, Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc., collectively WLF, seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. We, together with Jagotec have granted WLF a covenant not to sue with respect to US Patent Nos. 6,677,326 and 8,168,218, respectively, and accordingly these patents have been dismissed from the lawsuit. The court held a claim construction hearing on October 16, 2014, and issued its opinion and order on claim construction on November 10, 2014, adopting our proposed construction of both of the disputed claim terms. The court has scheduled expert discovery in the WLF
On November 13, 2014, we received a Paragraph IV Patent Certification from Watson advising that Watson had filed an ANDA with the FDA for a generic version of PENNSAID 2%. Watson has not advised us as to the timing or status of the FDA’s review of its filing. On December 23, 2014, we filed suit in the United States District Court for the District of New Jersey against Watson seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that Watson has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID 2% prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Watson’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The court has not yet set a trial date for the Watson action.

On December 2, 2014, we received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,741,956 from Paddock Laboratories, LLC, or Paddock, advising that Paddock had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On January 9, 2015, we received from Paddock another Paragraph IV Patent Certification against newly Orange Book listed U.S. Patent No. 8,871,809. Paddock has not advised us as to the timing or status of the FDA’s review of its filing. On January 13, 2015 and January 14, 2015, we filed suit in the United States District Court for the District of New Jersey and the United States District Court for the District of Delaware, respectively, against Paddock seeking an injunction to prevent the approval of the ANDA. The lawsuits allege that Paddock has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID 2% prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Paddock’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The courts have not yet set trial dates for the Paddock actions.

Currently, patent litigation is pending in the United States District Court for the District of New Jersey against four generic companies intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the United States District Court for the District of New Jersey and have been consolidated for discovery purposes. They are collectively known as the VIMOVO cases, and involve the following sets of defendants: (i) Dr. Reddy’s Laboratories Inc. and Dr. Reddy’s Laboratories Ltd. (collectively, Dr. Reddy’s); (ii) Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, Lupin); (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, Mylan); and (iv) Watson Laboratories, Inc.—Florida, known as Actavis Laboratories FL, Inc. and Actavis Pharma, Inc. (collectively, Actavis). Patent litigation in the United States District Court for the District of New Jersey against a fifth generic company, Anchen Pharmaceuticals Inc., or Anchen, was dismissed on June 9, 2014 after Anchen recertified under Paragraph III. We understand that Dr. Reddy’s has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy’s is now able to commercialize VIMOVO under AstraZeneca’s Nexium patent rights. The settlement agreement, however, has no effect on the Pozen VIMOVO patents, which are still the subject of patent litigations. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

The VIMOVO cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, January 4, 2013, May 10, 2013, June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We understand the Dr. Reddy’s notice letters were dated March 11, 2011 and November 20, 2012; the Lupin notice letters were dated June 10, 2011 and March 12, 2014; the Mylan notice letter was dated May 16, 2013; the Actavis notice letters were dated March 29, 2013 and
November 5, 2013; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order and has set a pretrial schedule but has not yet set a trial date.

On or about December 19, 2014, we filed a Notice of Opposition to a European patent, EP 2611457, to Roberto Testi, et al., covering compositions and methods for treating FA with interferon gamma, e.g., ACTIMMUNE. In the European Union, the grant of a patent may be opposed by one or more private parties.

On February 2, 2015, we received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, and 8,871,809 from Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd., or collectively Taro, advising that Taro had filed an ANDA with the FDA for a generic version of PENNSAID 2%. Taro has not advised us as to the timing or status of the FDA’s review of its filing. We are still in the process of evaluating the Paragraph IV Patent Certification, and it is anticipated we will file suit against Taro within the statute of limitations prescribed 45 day time limit.

Item 4. Mine Safety Disclosures

None.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

As a result of the Merger, all of the shares of Horizon Pharma, Inc. common stock issued and outstanding immediately prior to the effective time of the Merger were canceled and automatically converted into and became the right to receive our ordinary shares on a one-for-one basis and Horizon Pharma, Inc. became a wholly-owned subsidiary of Horizon Pharma plc.

Our ordinary shares began trading on The NASDAQ Global Market under the trading symbol “HZNP” on September 19, 2014. Previously, from July 28, 2011 until September 18, 2014, the common stock of Horizon Pharma, Inc. was traded on The NASDAQ Global Market also under the trading symbol “HZNP”. The following table sets forth the high and low sales prices per share of our ordinary shares (and for periods prior to September 19, 2014, the common stock of Horizon Pharma, Inc.) as reported on The NASDAQ Global Market for the periods indicated.

<table>
<thead>
<tr>
<th>Year</th>
<th>2014</th>
<th>2013</th>
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<tr>
<td>2014</td>
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<td></td>
<td>Second quarter</td>
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<td>16.56</td>
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<tr>
<td></td>
<td>Fourth quarter</td>
<td>13.55</td>
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Holders of Record

The closing price of our ordinary shares on February 20, 2015 was $18.53. As of February 20, 2015, there were approximately 17 holders of record of our ordinary shares.

Performance Graph

The following graph shows a comparison from July 28, 2011 (the date the common stock of Horizon Pharma, Inc. commenced trading on The NASDAQ Global Market) through December 31, 2013 or December 31, 2014, as applicable, of the cumulative total return for (i) our ordinary shares, (ii) the NASDAQ US Index, (iii) the NASDAQ Pharmaceutical Index, (iv) the NASDAQ US Benchmark TR Index and (v) NASDAQ Pharmaceuticals. As a result of a change in the total return data made available to us through our vendor provider, our performance graphs going forward will no longer include the NASDAQ US Index or the NASDAQ Pharmaceutical Index but instead will include the following comparable indexes provided by NASDAQ OMX Global Indexes: the NASDAQ US Benchmark TR Index and NASDAQ Pharmaceuticals. Information for NASDAQ US Index and NASDAQ Pharmaceutical Index is provided only through December 31, 2013, the last day this data was available from our third party index provider.

Information set forth in the graph below represents the performance of the Horizon Pharma, Inc. common stock from July 28, 2011 until September 18, 2014, the day before the consummation of the Merger, and the performance of our ordinary shares from September 19, 2014 through December 31, 2014. Our ordinary shares trade on the same exchange, the NASDAQ Global Market, and under the same trading symbol, “HZNP”, as the Horizon Pharma, Inc. common stock prior to the Merger. The graph assumes an initial investment of $100 on July 28, 2011. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of our ordinary shares.

The foregoing graph and table are furnished solely with this report, and are not filed with this report, and shall not be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Securities Act, or the Securities Exchange Act of 1934, as amended, whether made by us before or after the date hereof, regardless of any general incorporation language in any such filing, except to the extent we specifically incorporate this material by reference into any such filing.

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Dividend Policy

No cash dividends have ever been declared or paid on the common equity to date by Horizon Pharma, Inc. or us. We currently intend to retain all available funds and any future earnings to support operations and finance the growth and development of our business and do not intend to pay cash dividends on our ordinary shares for the foreseeable future. Under Irish law, dividends may only be paid, and share repurchases and redemptions must generally be funded only out of, “distributable reserves.” In addition, our ability to pay cash dividends is currently prohibited by the terms of our Senior Secured Credit Facility so long as we owe any amounts to the lenders under the credit agreement, subject to customary exceptions. Any future determination as to the payment of dividends will, subject to Irish legal requirements, be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements and other factors our board of directors deems relevant.

Securities Authorized for Issuance under Equity Compensation Plans

See Item 12 of Part III of this Annual Report on Form 10-K regarding information about securities authorized for issuance under our equity compensation plans.

Recent Sales of Unregistered Securities

We completed the following issuances of unregistered securities during the year ended December 31, 2014 which were not previously reported in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K:

• In November 2014, we issued 79,400 ordinary shares to BNY Mellon upon the cash exercise of a warrant and we received proceeds of $362,858.00 representing the aggregate exercise price of such warrant.
• In November 2014, we issued 109,700 ordinary shares to Enginebolt & CO via State Street upon the cash exercise of a warrant and we received proceeds of $501,329.00 representing the aggregate exercise price of such warrant.
• In November 2014, we issued 932,200 ordinary shares to Ball & CO FBO Fidelity Securities Fund upon the cash exercise of a warrant and we received proceeds of $4,260,154.00 representing the aggregate exercise price of such warrant.
• In November 2014, we issued 17,259 ordinary shares to Iroquois Master Fund upon the cash exercise of a warrant and we received proceeds of $74,351.77 representing the aggregate exercise price of such warrant.
• In December 2014, we issued 2,231 ordinary shares to Daniel Stauder upon the cashless exercise of a warrant to purchase an aggregate of 3,451 ordinary shares.

The offers, sales and issuances of the securities described above were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance on Rule 506 of Regulation D in that each issuance of securities was to an accredited investor under Rule 501 of Regulation D and did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and where appropriate, legends were affixed to the securities issued in these transactions.

Issuer Repurchases of Equity Securities

None.
Irish Law Matters

As a result of the Merger, the outstanding shares of the common stock of Horizon Pharma, Inc. were canceled and automatically converted into the right to receive our ordinary shares. As we are an Irish incorporated company, the following matters of Irish law are relevant to the holders of our ordinary shares.

Irish Restrictions on Import and Export of Capital. Except as indicated below, there are no restrictions imposed specifically on non-residents of Ireland dealing in Irish domestic securities, which includes ordinary shares of Irish companies. Dividends and redemption proceeds also continue to be freely transferable to non-resident holders of such securities. The Financial Transfers Act 1992 gives power to the Minister for Finance of Ireland to restrict financial transfers between Ireland and other countries and persons. Financial transfers are broadly defined and include all transfers that would be movements of capital or payments within the meaning of the treaties governing the member states of the European Union, or EU. The acquisition or disposal of interests in shares issued by an Irish incorporated company and associated payments falls within this definition. In addition, dividends or payments on redemption or purchase of shares and payments on a liquidation of an Irish incorporated company would fall within this definition. The Criminal Justice (Terrorist Offences) Act 2005 also gives the Minister for Finance of Ireland the power to take various measures, including the freezing or seizure of assets, in order to combat terrorism. At present the Financial Transfers Act 1992 and the Criminal Justice (Terrorist Offences) Act prohibits financial transfers involving the late Slobodan Milosevic and associated persons, Republic of Guinea-Bissau, Myanmar/Burma, Belarus, certain persons indicted by the International Criminal Tribunal for the former Yugoslavia, the late Osama bin Laden, Al-Qaeda, the Taliban of Afghanistan, Democratic Republic of Congo, Democratic People’s Republic of Korea (North Korea), Iran, Iraq, Côte d’Ivoire, Lebanon, Liberia, Zimbabwe, Sudan, Somalia, Republic of Guinea, Afghanistan, Egypt, Eritrea, Libya, Syria, Tunisia, certain known terrorists and terrorist groups, and countries that harbor certain terrorist groups, without the prior permission of the Central Bank of Ireland or the Minister of Finance (as applicable).

Any transfer of, or payment in respect of, a share or interest in a share involving the government of any country that is currently the subject of United Nations sanctions, any person or body controlled by any of the foregoing, or by any person acting on behalf of the foregoing, may be subject to restrictions pursuant to such sanctions as implemented into Irish law.

Irish Taxes Applicable to U.S. Holders

Witholding Tax on Dividends. While we have no current plans to pay dividends, dividends on our ordinary shares would generally be subject to Irish Dividend Withholding Tax, or DWT, at the standard rate of income tax (currently 20%), unless an exemption applies.

Dividends on our ordinary shares that are owned by residents of the United States and held beneficially through the Depositary Trust Company, or DTC, will not be subject to DWT provided that the address of the beneficial owner of the ordinary shares in the records of the broker is in the United States.

Dividends on our ordinary shares that are owned by residents of the United States and held directly (outside of DTC) will not be subject to DWT provided that the shareholder has completed the appropriate Irish DWT form and this form remains valid. Such shareholders must provide the appropriate Irish DWT form to our transfer agent at least seven business days before the record date for the first dividend payment to which they are entitled.

If any shareholder who is resident in the United States receives a dividend subject to DWT, he or she should generally be able to make an application for a refund from the Irish Revenue Commissioners on the prescribed form.

While the U.S./Ireland Double Tax Treaty contains provisions regarding withholding, due to the wide scope of the exemptions from DWT available under Irish domestic law, it would generally be unnecessary for a U.S. resident shareholder to rely on the treaty provisions.
Income Tax on Dividends. A shareholder who is neither resident nor ordinarily resident in Ireland and who is entitled to an exemption from DWT generally has no additional liability to Irish income tax or to the universal social charge on a dividend from us unless that shareholder holds our ordinary shares through a branch or agency in Ireland through which a trade is carried on.

A shareholder who is neither resident nor ordinarily resident in Ireland and who is not entitled to an exemption from DWT generally has no additional liability to Irish income tax or to the universal social charge on a dividend from us. The DWT deducted by us discharges the liability to Irish income tax and to the universal social charge. This however is not the case where the shareholder holds the ordinary shares through a branch or agency in Ireland through which a trade is carried on.

Irish Tax on Capital Gains. A shareholder who is neither resident nor ordinarily resident in Ireland and does not hold our ordinary shares in connection with a trade or business carried on by such shareholder in Ireland through a branch or agency should not be within the charge to Irish tax on capital gains on a disposal of our ordinary shares.

Capital Acquisitions Tax. Irish capital acquisitions tax, or CAT, is comprised principally of gift tax and inheritance tax. CAT could apply to a gift or inheritance of our ordinary shares irrespective of the place of residence, ordinary residence or domicile of the parties. This is because our ordinary shares are regarded as property situated in Ireland as our share register must be held in Ireland. The person who receives the gift or inheritance has primary liability for CAT.

CAT is levied at a rate of 33% above certain tax-free thresholds. The appropriate tax-free threshold is dependent upon (i) the relationship between the donor and the donee and (ii) the aggregation of the values of previous gifts and inheritances received by the donee from persons within the same category of relationship for CAT purposes. Gifts and inheritances passing between spouses are exempt from CAT. Our shareholders should consult their own tax advisers as to whether CAT is creditable or deductible in computing any domestic tax liabilities.

Stamp Duty. Irish stamp duty (if any) may become payable in respect of ordinary share transfers. However, a transfer of our ordinary shares from a seller who holds shares through DTC to a buyer who holds the acquired shares through DTC will not be subject to Irish stamp duty. A transfer of our ordinary shares (i) by a seller who holds ordinary shares outside of DTC to any buyer, or (ii) by a seller who holds the ordinary shares through DTC to a buyer who holds the acquired ordinary shares outside of DTC, may be subject to Irish stamp duty (currently at the rate of 1% of the price paid or the market value of the ordinary shares acquired, if greater). The person accountable for payment of stamp duty is the buyer or, in the case of a transfer by way of a gift or for less than market value, all parties to the transfer.

A shareholder who holds ordinary shares outside of DTC may transfer those ordinary shares into DTC without giving rise to Irish stamp duty provided that the shareholder would be the beneficial owner of the related book-entry interest in those ordinary shares recorded in the systems of DTC (and in exactly the same proportions) as a result of the transfer and at the time of the transfer into DTC there is no sale of those book-entry interests to a third party being contemplated by the shareholder. Similarly, a shareholder who holds ordinary shares through DTC may transfer those ordinary shares out of DTC without giving rise to Irish stamp duty provided that the shareholder would be the beneficial owner of the ordinary shares (and in exactly the same proportions) as a result of the transfer, and at the time of the transfer out of DTC there is no sale of those ordinary shares to a third party being contemplated by the shareholder. In order for the share registrar to be satisfied as to the application of this Irish stamp duty treatment where relevant, the shareholder must confirm to us that the shareholder would be the beneficial owner of the related book-entry interest in those ordinary shares recorded in the systems of DTC (and in exactly the same proportions) (or vice-versa) as a result of the transfer and there is no agreement for the sale of the related book-entry interest or the ordinary shares or an interest in the ordinary shares, as the case may be, by the shareholder to a third party being contemplated.
The selected statement of operations data for the years ended December 31, 2014, 2013 and 2012, and the balance sheet data as of December 31, 2014 and 2013 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected statement of operations data for the years ended December 31, 2011 and 2010, and the balance sheet data as of December 31, 2012, 2011 and 2010 have been derived from audited financial statements which are not included in this Annual Report on Form 10-K.

The following selected financial data also reflects the 1-for-2.374 reverse stock split of the outstanding shares of common stock of Horizon Pharma, Inc. effected in July 2011.

Our historical results are not necessarily indicative of future results. The selected financial data should be read in conjunction with "Management’s Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The selected financial data for periods prior to the year ended December 31, 2014 is that of Horizon Pharma, Inc., our predecessor, while the selected financial data for the year ended December 31, 2014 is that of Horizon Pharma plc.

### Selected Statement of Comprehensive Loss Data

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
<th>2011</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net sales</td>
<td>$296,955</td>
<td>$74,016</td>
<td>$18,844</td>
<td>$6,927</td>
<td>$2,376</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>78,753</td>
<td>14,625</td>
<td>11,875</td>
<td>7,267</td>
<td>4,263</td>
</tr>
<tr>
<td>Gross profit (loss)</td>
<td>218,202</td>
<td>59,391</td>
<td>6,969</td>
<td>(340)</td>
<td>(1,887)</td>
</tr>
<tr>
<td>Loss before benefit for income taxes</td>
<td>(269,687)</td>
<td>(150,126)</td>
<td>(92,965)</td>
<td>(127,948)</td>
<td>(27,725)</td>
</tr>
<tr>
<td>Net loss</td>
<td>(263,603)</td>
<td>(149,005)</td>
<td>(87,794)</td>
<td>(27,065)</td>
<td>(27,065)</td>
</tr>
</tbody>
</table>

### Selected Balance Sheet Data

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
<th>2011</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>$218,807</td>
<td>$80,480</td>
<td>$104,087</td>
<td>$17,966</td>
<td>$5,384</td>
</tr>
<tr>
<td>Working capital (deficit)</td>
<td>106,833</td>
<td>67,455</td>
<td>79,983</td>
<td>1,065</td>
<td>(17,944)</td>
</tr>
<tr>
<td>Total assets</td>
<td>1,134,624</td>
<td>252,596</td>
<td>193,984</td>
<td>101,078</td>
<td>161,685</td>
</tr>
<tr>
<td>Total debt, net of debt discount</td>
<td>345,503</td>
<td>110,762</td>
<td>48,801</td>
<td>19,438</td>
<td>24,615</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(720,719)</td>
<td>(457,116)</td>
<td>(308,111)</td>
<td>(220,317)</td>
<td>(107,052)</td>
</tr>
<tr>
<td>Total shareholders’ equity (deficit)</td>
<td>540,204</td>
<td>(49,082)</td>
<td>105,978</td>
<td>45,912</td>
<td>97,056</td>
</tr>
</tbody>
</table>

### Selected Statement of Cash Flows Data

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
<th>2011</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net cash provided by (used in) operating activities</td>
<td>$27,549</td>
<td>(54,287)</td>
<td>(76,641)</td>
<td>(41,540)</td>
<td>(37,532)</td>
</tr>
<tr>
<td>Net cash (used in) provided by investing activities</td>
<td>(227,720)</td>
<td>(36,135)</td>
<td>(1,386)</td>
<td>(2,154)</td>
<td>5,575</td>
</tr>
<tr>
<td>Net cash provided by financing activities</td>
<td>338,285</td>
<td>66,716</td>
<td>164,308</td>
<td>55,152</td>
<td>29,760</td>
</tr>
<tr>
<td>Payments for acquisitions, net of cash acquired</td>
<td>(224,220)</td>
<td>(35,000)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Net proceeds from the issuance of common stock</td>
<td>41,934</td>
<td>6,637</td>
<td>128,518</td>
<td>44,678</td>
<td>—</td>
</tr>
<tr>
<td>Net proceeds from the issuance of debt</td>
<td>286,966</td>
<td>143,598</td>
<td>55,578</td>
<td>23,417</td>
<td>21,960</td>
</tr>
<tr>
<td>Repayment of notes payable</td>
<td>—</td>
<td>64,844</td>
<td>19,788</td>
<td>13,067</td>
<td>10,981</td>
</tr>
</tbody>
</table>
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the “Risk Factors” section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

The discussion below contains “forward-looking statements,” as defined in Section 21E of the Securities Exchange Act of 1934, as amended, that reflect our current expectations regarding our future growth, results of operations, cash flows, performance and business prospects and opportunities, as well as assumptions made by, and information currently available to, our management. We have tried to identify forward-looking statements by using words such as “anticipate,” “believe,” “plan,” “expect,” “intend,” “will,” and similar expressions, but these words are not the exclusive means of identifying forward-looking statements. These statements are based on information currently available to us and are subject to various risks, uncertainties, and other factors, including, but not limited to, those matters discussed in Item 1A. “Risk Factors” in Part I of this Annual Report on Form 10-K, that could cause our actual growth, results of operations, cash flows, performance and business prospects and opportunities to differ materially from those expressed in, or implied by, these statements. Except as expressly required by the federal securities laws, we undertake no obligation to update such factors or to publicly announce the results of any of the forward-looking statements contained herein to reflect future events, developments, or changed circumstances, or for any other reason.

OVERVIEW

Merger with Vidara

On September 19, 2014, the businesses of Horizon Pharma Inc., or HPI, and Vidara Therapeutics International Public Limited Company, or Vidara, were combined in a merger transaction, or the Merger, accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with HPI treated as the acquiring company in the Merger for accounting purposes. As part of the Merger, a wholly-owned subsidiary of Vidara merged with and into HPI, with HPI surviving the Merger as a wholly-owned subsidiary of Vidara and Vidara changed its name to Horizon Pharma plc, or New Horizon. Upon the consummation of the Merger, the historical financial statements of HPI became our historical financial statements. Accordingly, the historical financial statements of HPI are included in the comparative prior periods.

Unless otherwise indicated or the context otherwise requires, references to the “Company”, “New Horizon”, “we”, “us” and “our” refer to Horizon Pharma plc and its consolidated subsidiaries, including its predecessor, HPI. All references to “Vidara” are references to Horizon Pharma plc (formerly known as Vidara Therapeutics International Public Limited Company) and its consolidated subsidiaries prior to the effective time of the Merger on September 19, 2014. The disclosures in this report relating to the pre-Merger business of Horizon Pharma plc, unless noted as being the business of Vidara prior to the Merger, pertain to the business of HPI prior to the Merger.

Our Business

We are a specialty biopharmaceutical company focused on improving patients’ lives by identifying, developing, acquiring or in-licensing and commercializing differentiated products that address unmet medical needs. We market a portfolio of products in arthritis, inflammation and orphan diseases. Our U.S. marketed products are ACTIMMUNE® (interferon gamma-1b), DUEXIS® (ibuprofen/famotidine), PENNSAID® (diclofenac sodium topical solution) 2% w/w, RAYOS® (prednisone) delayed-release tablets and VIMOVO®.
We developed DUEXIS and RAYOS, acquired the U.S. rights to VIMOVO from AstraZeneca AB, or AstraZeneca, in November 2013, acquired the U.S. rights to ACTIMMUNE as a result of the Merger and acquired the U.S. rights to PENNSAID 2% from Nuvo Research Inc., or Nuvo, in October 2014, which we began marketing in the United States in January 2015. We market our products in the United States through our field sales force of approximately 375 representatives, consisting of approximately 325 primary care sales representatives and 50 sales representatives in our specialty and orphan diseases business areas. Our strategy is to utilize the commercial strength and infrastructure we have established in creating a fully-integrated U.S.-focused specialty biopharmaceutical company to continue the successful commercialization of our existing product portfolio while also expanding and leveraging these capabilities further.

On April 23, 2011, the U.S. Food and Drug Administration, or FDA, approved DUEXIS, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis, or RA, osteoarthritis, or OA, and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for these indications. We began marketing DUEXIS to physicians in December 2011. In June 2012, we licensed DUEXIS rights in Latin America to Grünenthal S.A., a private company focused on the promotion of pain products. Grünenthal S.A. is currently in the registration process for the commercialization of DUEXIS in Latin America.

Our second approved product in the United States, RAYOS, known as LODOTRA® outside the United States, is a proprietary delayed-release formulation of low-dose prednisone, first approved in Europe in March 2009, for the treatment of moderate to severe, active RA in adults, particularly when accompanied by morning stiffness. On July 26, 2012, the FDA approved RAYOS for the treatment of RA, polymyalgia rheumatica, or PMR, psoriatic arthritis, ankylosing spondylitis, or AS, asthma and chronic obstructive pulmonary disease and a number of other conditions. We began marketing DUEXIS to physicians in December 2011. In June 2012, we licensed DUEXIS rights in Latin America to Grünenthal S.A., a private company focused on the promotion of pain products. Grünenthal S.A. is currently in the registration process for the commercialization of DUEXIS in Latin America.

On November 18, 2013, we entered into agreements with AstraZeneca pursuant to which we acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with non-steroidal anti-inflammatory drugs, or NSAIDs, in the United States. VIMOVO (naproxen/esomeprazole magnesium) is a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a proton pump inhibitor, layer surrounding the core. VIMOVO was originally developed by Pozen Inc., or Pozen, together with AstraZeneca pursuant to an exclusive global collaboration and license agreement. On April 30, 2010, the FDA approved VIMOVO for the relief of the signs and symptoms of OA, RA, and AS and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.

We announced the availability of Horizon-labeled VIMOVO on January 2, 2014, at which time we also began marketing VIMOVO with our primary care sales force.

On March 18, 2014, HPI, Vidara Therapeutics Holdings LLC, a Delaware limited liability company, or Vidara Holdings, Vidara, Hamilton Holdings (USA), Inc., a Delaware corporation and an indirect wholly-owned subsidiary of Vidara, or U.S. HoldCo, and Hamilton Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of U.S. HoldCo, or Merger Sub, entered into a Transaction Agreement and Plan of Merger, or the Merger Agreement. The Merger Agreement provided for the merger of Merger Sub with and into HPI, with HPI continuing as the surviving corporation and as a wholly-owned, indirect subsidiary of Vidara, with Vidara converting to a public limited company and changing its name to Horizon Pharma plc. As a result of the Merger, we are organized under the laws of Ireland. Upon consummation of the Merger, New Horizon made a cash
payment of $210.9 million to Vidara Holdings and $2.7 million to Citibank N.A. as escrow agent under an escrow agreement associated with the Merger. The majority of the escrowed funds were released during January 2015 in accordance with the terms of the escrow agreement.

In connection with the Merger, on June 17, 2014, HPI entered into a $300.0 million five-year senior secured credit facility, or Senior Secured Credit Facility, with certain lenders and Citibank, N.A., as administrative agent and collateral agent. HPI used the proceeds of the Senior Secured Credit Facility to provide the cash payment of $213.6 million for Vidara and to pay certain transaction related expenses, and we are using the balance for general corporate purposes.

As a result of the Merger, we began marketing ACTIMMUNE, a bioengineered form of interferon gamma-1b, a protein that acts as a biologic response modifier, in the United States. ACTIMMUNE is approved by the FDA for use in children and adults with chronic granulomatous disease, or CGD, and severe, malignant osteopetrosis, or SMO. ACTIMMUNE is indicated for reducing the frequency and severity of serious infections associated with CGD and for delaying time to disease progression in patients with SMO. We also plan to study ACTIMMUNE for potential additional indications, and the FDA has agreed to the primary endpoint for a Phase 3 study that will evaluate ACTIMMUNE in the treatment of Friedreich’s Ataxia, or FA. In February 2015, we submitted an IND application and we anticipate the Phase 3 clinical study will begin enrolling patients in the second quarter of 2015.

On October 17, 2014, we acquired the U.S. rights to PENNSAID 2% from Nuvo for $45.0 million in cash. PENNSAID 2% is approved in the United States for the treatment of the pain of OA of the knee(s). As part of the acquisition, we entered into an exclusive eight-year supply agreement under which Nuvo will supply us product. We began marketing PENNSAID 2% in January 2015 and included PENNSAID 2% in our Prescriptions Made Easy, or PME, specialty pharmacy program. In connection with our acquisition of PENNSAID 2%, we expanded our primary care sales force by 75 additional representatives. Our primary care representatives are now marketing DUEXIS, PENNSAID 2% and VIMOVO.
RESULTS OF OPERATIONS
Year Ended December 31, 2014 Compared to Year Ended December 31, 2013

<table>
<thead>
<tr>
<th></th>
<th>For the Years Ended December 31,</th>
<th>Increase / (Decrease)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2014 (in thousands)</td>
<td>2013</td>
</tr>
<tr>
<td>Net sales</td>
<td>$296,955</td>
<td>$74,016</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>78,753</td>
<td>14,625</td>
</tr>
<tr>
<td>Gross profit</td>
<td>218,202</td>
<td>59,391</td>
</tr>
<tr>
<td>Operating expenses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>17,460</td>
<td>10,084</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>120,276</td>
<td>68,595</td>
</tr>
<tr>
<td>General and administrative</td>
<td>88,957</td>
<td>23,566</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>226,693</td>
<td>102,245</td>
</tr>
<tr>
<td>Operating loss</td>
<td>(8,491)</td>
<td>(42,854)</td>
</tr>
<tr>
<td>Other income (expense), net:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(23,826)</td>
<td>(12,774)</td>
</tr>
<tr>
<td>Foreign exchange (loss) gain</td>
<td>(3,905)</td>
<td>1,206</td>
</tr>
<tr>
<td>Loss on derivative fair value</td>
<td>(214,995)</td>
<td>(69,300)</td>
</tr>
<tr>
<td>Loss on induced conversion and debt extinguishment</td>
<td>(29,390)</td>
<td>(26,404)</td>
</tr>
<tr>
<td>Bargain purchase gain</td>
<td>22,171</td>
<td>—</td>
</tr>
<tr>
<td>Other expense</td>
<td>(11,251)</td>
<td>—</td>
</tr>
<tr>
<td>Total other expense, net</td>
<td>(261,196)</td>
<td>(107,272)</td>
</tr>
<tr>
<td>Loss before benefit for income taxes</td>
<td>(269,687)</td>
<td>(150,126)</td>
</tr>
<tr>
<td>Benefit for income taxes</td>
<td>(6,084)</td>
<td>(1,121)</td>
</tr>
<tr>
<td>Net loss</td>
<td>$263,603</td>
<td>($149,005)</td>
</tr>
</tbody>
</table>

Net sales. Net sales increased $222.9 million, or 301%, to $297.0 million during the year ended December 31, 2014, from $74.0 million during the year ended December 31, 2013.

The following table reflects the components of net sales for the years ended December 31, 2014 and 2013:

<table>
<thead>
<tr>
<th></th>
<th>Year Ended December 31,</th>
<th>Change $</th>
<th>Change %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2014 (in thousands)</td>
<td>2013</td>
<td></td>
</tr>
<tr>
<td>VIMOVO</td>
<td>$162,954</td>
<td>$966</td>
<td>$161,988</td>
</tr>
<tr>
<td>DUEXIS</td>
<td>83,243</td>
<td>58,972</td>
<td>24,271</td>
</tr>
<tr>
<td>ACTIMMUNE</td>
<td>25,251</td>
<td>—</td>
<td>25,251</td>
</tr>
<tr>
<td>RAYOS</td>
<td>19,020</td>
<td>5,841</td>
<td>13,179</td>
</tr>
<tr>
<td>LODOTRA</td>
<td>6,487</td>
<td>8,237</td>
<td>(1,750)</td>
</tr>
<tr>
<td>Total Net Sales</td>
<td>$296,955</td>
<td>$74,016</td>
<td>$222,939</td>
</tr>
</tbody>
</table>

* Percentage change is not meaningful.

The increase in net sales during the year ended December 31, 2014 was primarily due to growth in net sales of DUEXIS, our initiation of VIMOVO sales in January 2014 and our recognition of ACTIMMUNE sales following the acquisition of Vidara in September 2014.
VIMOVO. Net sales increased $162.0 million to $163.0 million during the year ended December 31, 2014, from $1.0 million during the year ended December 31, 2013. We began marketing of VIMOVO with our sales force in November 2013 and began selling Horizon-labeled VIMOVO in January 2014.

DUEXIS. Net sales increased $24.3 million, or 41%, to $83.2 million during the year ended December 31, 2014, from $59.0 million during the year ended December 31, 2013. In 2014, DUEXIS net sales increased approximately $39.2 million as the result of prescription volume growth driven by the expansion of our field sales force and the continued rollout of our PME program, partially offset by $15.1 million due to lower net pricing. Although DUEXIS selling prices increased, the higher selling prices were offset by increased rebates and patient co-pay reimbursements as a result of our PME program.

ACTIMMUNE. Net sales were $25.3 million during the year ended December 31, 2014 compared to no net sales during the year ended December 31, 2013. Our 2014 net sales represent sales during the period following the Merger on September 19, 2014.

RAYOS. Net sales increased $13.2 million, or 226%, to $19.0 million during the year ended December 31, 2014, from $5.8 million during the year ended December 31, 2013. Approximately $9.0 million of the increase in RAYOS net sales was the result of net price increases and $4.2 million was due to prescription volume growth driven by the expansion of our sales force and the continued rollout of our PME program.

LODOTRA. Net sales decreased $1.7 million, or 21%, to $6.5 million during the year ended December 31, 2014, from $8.2 million during the year ended December 31, 2013. The decrease was the result of $1.5 million from reduced product shipments to our European distribution partner, Mundipharma, and $0.2 million in lower amortization of milestone payments. LODOTRA shipments to Mundipharma are not linear or directly tied to Mundipharma’s in-market sales and can therefore fluctuate significantly from quarter to quarter.

We currently expect our net sales to increase in 2015 and future periods as a result of both price and volume increases. Effective January 1, 2015, we have increased the price for both DUEXIS and VIMOVO by 35.8%, for RAYOS by 28.0% and for ACTIMMUNE by 9.0%. While we believe these price increases should favorably impact net sales during 2015, they will be offset in part by additional sales allowances related to rebates and patient co-pay reimbursements. We may affect further price increases for these products and/or other products in 2015 and future periods in response to future market conditions.

Effective January 1, 2015, two significant pharmacy benefit managers, or PBMs, placed DUEXIS and VIMOVO on their exclusion lists, which will result in a loss of reimbursement for patient’s whose healthcare plans have adopted these PBM exclusion lists. As a result, DUEXIS and VIMOVO may face negative pressure on prescription volume. We expect that continued adoption of our PME program by physicians will be important to our ability to counter this action by the two PBMs and to offset pressure from healthcare payors and PBMs to use less expensive generic or over the counter brands instead of our branded products.

We have expanded and may continue to expand our sales force to support existing and newly acquired products, such as PENNSAID 2%, which we acquired in October 2014 and began marketing in January 2015. As result of the Merger and our acquisition of PENNSAID 2%, we expanded our sales force to approximately 375 sales representatives, consisting of 325 primary care sales representatives and 50 sales representatives in specialty and orphan diseases business areas.

Cost of Goods Sold. Cost of goods sold increased $64.1 million to $78.8 million during the year ended December 31, 2014, from $14.6 million during the year ended December 31, 2013. As a percentage of net sales, cost of goods sold was 26.5% in 2014 compared to 19.8% in 2013. The increase in cost of goods sold was primarily attributable to a $9.1 million increase in product costs due to higher DUEXIS and VIMOVO sales, an increase in intangible amortization expense of $24.2 million, an $11.1 million charge to recognize additional cost.
During the second quarter of 2014, based on higher sales of VIMOVO during the six months ended June 30, 2014 versus our original expectations and our adjusted expectations for future VIMOVO sales, we recorded a charge of $13.0 million to cost of goods sold to increase the amount of the estimated contingent royalty liability to reflect the updated projections. During the fourth quarter of 2014, after our most recent five year plan was approved, we performed an assessment of the carrying value of the contingent royalty liability, which resulted in a $3.6 million adjustment to cost of goods sold to reduce the amount of the contingent royalty liability to reflect our updated estimates. As a result, for the year ended December 31, 2014 we recorded a net charge of $9.4 million to cost of goods sold and a corresponding increase to the contingent royalty liability to reflect the estimated fair value of the future contingent royalties payable to Pozen.

During the fourth quarter of 2014, as the result of a price increase for ACTIMMUNE approved to take effect on January 1, 2015, we reassessed the value of our estimated royalty liability and recorded a charge of $1.3 million to cost of goods sold to increase the carrying value of the contingent royalties to reflect the updated projections.

Intangible amortization increased $24.2 million during the year ended December 31, 2014 compared to the prior year period as a result of an increase of $11.8 million of which was attributable to a full year of intangible amortization expense related to VIMOVO developed technology and $12.2 million of which was related to amortization of developed technology for ACTIMMUNE as a result of the Merger. We expect $43.1 million of amortization expense for ACTIMMUNE in 2015.

Research and Development Expenses. Research and development expenses increased $7.4 million to $17.5 million during the year ended December 31, 2014, from $10.1 million during the year ended December 31, 2013. The increase in research and development expenses during the year ended December 31, 2014 was primarily associated with $2.3 million in research and development expenses for ACTIMMUNE, $2.1 million in higher salaries and benefits expense, $1.7 million in increased clinical expenses and $1.2 million in higher consulting fees.

Sales and Marketing Expenses. Sales and marketing expenses increased $51.7 million to $120.3 million during the year ended December 31, 2014, from $68.6 million during the year ended December 31, 2013. The increase in sales and marketing expenses was primarily attributable to an increase of $34.5 million in salaries and benefits expenses associated with increased staffing of our field sales force, $13.2 million in higher marketing and commercialization expenses primarily related to ACTIMMUNE and VIMOVO, $2.5 million in higher facility expenses and $1.1 million in higher consulting fees.

General and Administrative Expenses. General and administrative expenses increased $65.4 million to $89.0 million during the year ended December 31, 2014, from $23.6 million during the year ended December 31, 2013. The increase in general and administrative expenses was primarily attributable to a $40.2 million increase in legal, consulting and investment advisory fees and other costs associated with the Merger and related financing transactions, a $20.3 million increase in salaries and benefits expense as a result of increased staffing of our administrative and finance functions and a $2.9 million increase in related facilities expenses.

Interest Expense, Net. Interest expense, net increased $11.1 million to $23.8 million during the year ended December 31, 2014, from $12.8 during the year ended December 31, 2013. The increased interest expense, net was primarily due to higher borrowings under our Convertible Senior Notes and Senior Secured Credit Facility during the year ended December 31, 2014, as compared to our prior borrowings under our Senior Secured Loan.

Foreign Exchange (Loss) Gain. During the year ended December 31, 2014, we reported a foreign exchange loss of $3.9 million compared to a foreign exchange gain of $1.2 million during the year ended December 31,
2013. The foreign exchange loss during the year ended December 31, 2014 was primarily attributable to a weakening of the Euro against the U.S. dollar which impacted our Swiss subsidiary, Horizon Pharma AG, whose functional currency is in Euros, yet has intercompany balances and intercompany transactions as well as third-party transactions that are denominated in U.S. dollars.

**Loss on Derivative Revaluation.** During the year ended December 31, 2014, we recorded a $215.0 million non-cash charge compared to $69.3 million non-cash charge recorded during the year ended December 31, 2013. The increase in non-cash charges during the year ended December 31, 2014 was a result of the increase in the fair value of the embedded derivative associated with our Convertible Senior Notes. The increase in loss on the derivative revaluation was primarily due to an increase in the market value of HPI's common stock during the period from January 1, 2014 through June 27, 2014, the date HPI's stockholders approved the issuance of common equity in excess of 13,164,951 shares upon conversion of the Convertible Senior Notes. The non-cash loss on derivative revaluation was a permanent tax difference and was not deductible for income tax reporting purposes.

**Loss on Induced Conversion and Debt Extinguishment.** The loss on induced conversion and debt extinguishment during the year ended December 31, 2014 of $29.4 million was a result of the Convertible Senior Notes induced conversions in the fourth quarter of 2014, which consisted of $16.7 million of loss on induced conversion for cash inducement payments, a $11.7 million charge for the extinguishment of debt and $1.0 million of expenses related to the induced debt conversions. The loss on induced conversion and debt extinguishment during the year ended December 31, 2013 of $26.4 million was related to the extinguishment of our Senior Secured Loan in November 2013.

**Bargain Purchase Gain.** During the year ended December 31, 2014, we recorded a bargain purchase gain of $22.2 million in connection with the Merger, representing the excess of the estimated fair values of net assets acquired over the acquisition consideration paid.

**Other Expense.** Other expense during the year ended December 31, 2014 totaled $11.3 million, which represented $5.0 million of commitment fees incurred on a bridge loan commitment prior to executing the Senior Secured Credit Facility in June 2014, $3.2 million of commitment fees incurred on the Senior Secured Credit Facility prior to its funding on September 19, 2014 and $2.9 million of secondary offering expense fees incurred in the November 2014 underwritten public offering.

**Income Tax Benefit.** During the years ended December 31, 2014 and 2013, we recorded a benefit for income taxes of $6.1 million and $1.1 million, respectively. The increase in income tax benefit during the year ended December 31, 2014 was primarily attributable to a deferred tax asset valuation adjustment of $3.0 million recorded during the third quarter of 2014. The inclusion of additional deferred tax liabilities as a result of the Merger resulted in our ability to reduce our existing deferred tax valuation allowance, which correspondingly resulted in our ability to record an additional income tax benefit of $3.0 million.

**Net Loss.** Net loss increased $114.6 million to $263.6 million during the year ended December 31, 2014, from $149.0 million during the year ended December 31, 2013, primarily as a result of the loss on derivative revaluation during the year ended December 31, 2014.
Net Sales. Net sales increased 293% to $74.0 million for the year ended December 31, 2013 as compared to $18.8 million for the year ended December 31, 2012.

The following table reflects the components of net sales for the years ended December 31, 2013 and 2012:

<table>
<thead>
<tr>
<th></th>
<th>For the Years Ended December 31, 2013</th>
<th>Increase / (Decrease)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
<td>2012</td>
</tr>
<tr>
<td>Net sales</td>
<td>$ 74,016</td>
<td>$ 18,844</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>14,625</td>
<td>11,875</td>
</tr>
<tr>
<td>Gross profit</td>
<td>59,391</td>
<td>6,969</td>
</tr>
<tr>
<td>Operating expenses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>10,084</td>
<td>16,837</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>68,595</td>
<td>49,561</td>
</tr>
<tr>
<td>General and administrative</td>
<td>23,566</td>
<td>19,444</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>102,245</td>
<td>85,842</td>
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<tr>
<td>Operating loss</td>
<td>(42,854)</td>
<td>(78,873)</td>
</tr>
<tr>
<td>Other income (expense), net:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(12,774)</td>
<td>(11,552)</td>
</tr>
<tr>
<td>Foreign exchange gain</td>
<td>1,206</td>
<td>489</td>
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<tr>
<td>Loss on derivative fair value</td>
<td>(69,300)</td>
<td>—</td>
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<tr>
<td>Loss on debt extinguishment</td>
<td>(26,404)</td>
<td>(2,973)</td>
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<tr>
<td>Other expense</td>
<td>—</td>
<td>(56)</td>
</tr>
<tr>
<td>Total other expense, net</td>
<td>(107,272)</td>
<td>(14,092)</td>
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<tr>
<td>Loss before benefit for income taxes</td>
<td>(150,126)</td>
<td>(92,965)</td>
</tr>
<tr>
<td>Benefit for income taxes</td>
<td>(1,121)</td>
<td>(5,171)</td>
</tr>
<tr>
<td>Net loss</td>
<td>$(149,005)</td>
<td>$(87,794)</td>
</tr>
</tbody>
</table>

* Percentage change is not meaningful.

Net sales increased by $55.2 million, or 293%, to $74.0 million in 2013 compared to $18.8 million in 2012. The net sales increase was primarily due to growth in net sales of DUEXIS and RAYOS.

**DUEXIS**. Net sales increased by $48.7 million, or 472%, to $59.0 million in 2013 compared to $10.3 million in 2012. Approximately $40.1 million of the increase in DUEXIS net sales was the result of net price increases and $8.6 million was due to volume growth driven by the expansion of our sales force.
LODOTRA. Net sales were $8.2 million in both 2013 and 2012. LODOTRA net sales increased $0.7 million related to amortization of milestone payments offset by a $0.7 million decrease in net sales for product shipments to our European distribution partner, Mundipharma. LODOTRA shipments to Mundipharma are not linear or directly tied to Mundipharma’s in-market sales and can therefore fluctuate significantly from quarter to quarter.

RAYOS. Net sales increased by $5.5 million, or 1,833%, to $5.8 million in 2013 compared to $0.3 million in 2012. Approximately $4.7 million of the increase in RAYOS net sales was the result of net price increases and $0.8 million was due to volume growth driven by the expansion of our sales force.

VIMOVO. Net sales were $1.0 million in 2013. We began marketing of VIMOVO with our sales force on November 26, 2013.

Cost of Goods Sold. Cost of goods sold increased $2.7 million to $14.6 million during the year ended December 31, 2013, from $11.9 million during the year ended December 31, 2012. As a percentage of net sales, cost of goods sold was 19.8% during the year ended December 31, 2013 compared to 63.0% during the year ended December 31, 2012. The increase in cost of goods sold did not increase proportionately with the increase in net sales primarily due to net price increases, which do not correspondingly increase cost of goods sold, driving most of the net sales increase. As discussed above, DUEXIS and RAYOS net sales in 2013 increased by $40.1 million and $4.7 million, respectively, as a result of net price increases.

The increase in cost of goods sold was primarily attributable to a $3.4 million increase in intangible amortization expense. The increase in amortization expense was related to the FDA approval of RAYOS in July 2012, which resulted in the reclassification and subsequent amortization of an indefinite-lived intangible asset to a finite-lived intangible asset, which resulted in additional intangible amortization expense of $2.0 million during the year ended December 31, 2013 as a result of a full year of amortization as compared to 2012. Additionally, as a result of our asset purchase agreement with AstraZeneca, we capitalized $67.7 million in intangible assets related to the VIMOVO intellectual property rights. This intangible asset will be amortized using a straight-line method over its estimated useful life of 61.5 months. During the year ended December 31, 2013, we recorded $1.6 million in intangible amortization expense related to the intellectual property acquired in connection with our acquisition of the U.S. rights to VIMOVO. For the years ended December 31, 2013 and 2012, intangible amortization expense accounted for 56% and 40%, respectively, of total cost of goods sold.

Research and Development Expenses. Research and development expenses during the year ended December 31, 2013 were $10.1 million, a decrease of $6.7 million compared to research and development expenses of $16.8 million during the year ended December 31, 2012. The decrease in research and development expenses during the year ended December 31, 2013 was primarily associated with the classification of $5.0 million in medical affairs expenses to sales and marketing expenses, a $0.9 million reduction in consulting fees and a $0.8 million decrease in regulatory and clinical trial expenses. During the first quarter of 2013, in connection with the full commercial launch of RAYOS, we began to classify our medical affairs expenses, which consist of expenses related to scientific publications, health outcomes, biostatistics, medical education and information, and medical communications, as sales and marketing expenses. Prior to the full commercial launch of RAYOS in late January 2013, medical affairs expenses were classified as part of research and development expenses.

Sales and Marketing Expenses. Sales and marketing expenses during the year ended December 31, 2013 were $68.6 million, an increase of $19.0 million compared to sales and marketing expenses of $49.6 million during the year ended December 31, 2012. The increase in sales and marketing expenses was primarily attributable to an increase of $13.6 million in salaries and benefits expenses due to the increase in staffing of our field sales force and the inclusion of $5.0 million of medical affairs expenses in sales and marketing expenses.

General and Administrative Expenses. General and administrative expenses during the year ended December 31, 2013 were $23.6 million, an increase of $4.2 million compared to general and administrative
expenses of $19.4 million during the year ended December 31, 2012. The increase in general and administrative expenses was primarily due to $1.9 million in additional salaries and related benefits expense associated with incremental finance and administrative staff compared to the prior year, $1.8 million in higher legal expenses, which consisted of a $1.1 million increase in legal fees incurred in connection with our VIMOVO asset acquisition and a $0.7 million increase in legal fees associated with intellectual property related matters. Additionally, facilities expense increased $0.7 million in the year ended December 31, 2013 as a result of additional information technology infrastructure expenses related to the expansion of our field sales force.

Interest Expense, Net. Interest expense, net was $12.8 million during the year ended December 31, 2013, an increase of $1.2 million compared to interest expense, net of $11.6 million during the year ended December 31, 2012. The increase in interest expense, net was primarily attributable to higher interest expense related to the amortization of deferred financing and debt discount expenses.

Foreign Exchange Gain. During the years ended December 31, 2013 and 2012, we reported a foreign exchange gain of $1.2 million and $0.5 million, respectively. The foreign exchange gain in each period was primarily attributable to an increase in the value of the Euro against the U.S. dollar compared to the applicable prior year, which resulted in a favorable currency impact for our Swiss subsidiary, Horizon Pharma AG.

Loss on Derivative Revaluation. During the year ended December 31, 2013, we recorded a $69.3 million non-cash charge related to the increase in the fair value of the embedded derivatives in the Convertible Senior Notes we issued in November 2013, principally due to an increase in the market value of HPI’s common stock during the period from issuance to December 31, 2013.

Loss on Debt Extinguishment. During the year ended December 31, 2013, we recorded a $26.4 million charge related to the extinguishment of our Senior Secured Loan in November 2013 compared to loss on debt extinguishment of a prior debt facility of $3.0 million during the year ended December 31, 2012.

Income Tax Benefit. Income tax benefit was $1.1 million during the year ended December 31, 2013, a decrease of $4.1 million compared to an income tax benefit of $5.2 million during the year ended December 31, 2012. The decrease in income benefit during the year ended December 31, 2013 was primarily attributable to the absence of a one-time tax benefit which was recorded during the year ended December 31, 2012. On July 26, 2012, the FDA approved RAYOS, which resulted in the reclassification of the entire asset balance of $35.5 million, from an indefinite-lived intangible asset to a finite-lived intangible asset. The reclassification from an indefinite-lived intangible asset to a finite-lived intangible asset required us to amortize this asset over the useful life of the asset, which resulted in a corresponding reduction to our net deferred tax liabilities and the recognition of a one-time net income tax benefit of $4.3 million that was recorded during the third quarter of 2012.

Liquidity and Capital Resources

We have incurred losses since our inception in June 2005 and, as of December 31, 2014, we had an accumulated deficit of $720.7 million. While we incurred a significant net loss in 2014, primarily due to the loss from derivative revaluation, loss from induced debt conversion and costs associated with the Merger, we did generate positive cash inflows from operating activities of $27.5 million. We expect that our sales and marketing expenses will continue to increase as a result of our commercialization of ACTIMMUNE, DUEXIS, PENNSAID 2%, RAYOS/LODOTRA and VIMOVO, but we believe these costs will be more than offset by higher net sales and gross profits and we expect our current operations to achieve profitability in 2015.

We have financed our operations to date through equity financings, debt financings and the issuance of convertible notes. As of December 31, 2014, we had $218.8 million in cash and cash equivalents and total debt with a book value of $345.5 million and face value of $361.0 million. We believe we will generate sufficient cash flows from our operations to fund our business needs. As noted in Part I — Item 1. “Business — Overview”
above, part of our strategy is to expand and leverage our commercial capabilities by identifying, developing, acquiring and commercializing additional differentiated products that address unmet medical needs. To the extent we enter into transactions to acquire products or businesses in the future, we will most likely need to finance a significant portion of those acquisitions through additional debt, equity or convertible debt financings.

On March 18, 2014, HPI, Vidara Holdings, Vidara, U.S. HoldCo and Merger Sub entered into the Merger Agreement under which Merger Sub merged with and into HPI, with HPI continuing as the surviving corporation and as a wholly-owned, indirect subsidiary of Vidara, and with Vidara converting to a public limited company and changing its name to Horizon Pharma plc. Following the completion of the Merger, New Horizon is organized under the laws of Ireland. In the Merger, HPI’s stockholders received one ordinary share of New Horizon in exchange for each share of HPI common stock they owned as of the closing. Upon the closing of the Merger, HPI’s security holders (excluding the holders of the Convertible Senior Notes) owned approximately 74% of New Horizon and Vidara Holdings owned approximately 26% of New Horizon on a fully-diluted basis. At the closing, Vidara Holdings received a cash payment of $210.9 million and $2.7 million was paid into a temporary escrow account. The majority of the escrowed funds were released during January 2015 in accordance with the terms of the escrow agreement.

On March 18, 2014, HPI entered into a commitment letter, or the Commitment Letter, with Deerfield Management Company, L.P., or Deerfield, and certain funds managed by Deerfield, or the Deerfield Funds, pursuant to which the Deerfield Funds committed to provide up to $250.0 million of senior secured loans to finance the Merger. HPI allowed the Commitment Letter to expire on June 30, 2014 as a result of the execution of the Senior Secured Credit Facility.
On November 18, 2013, we entered into note purchase agreements with investors to issue $150.0 million aggregate principal amount of Convertible Senior Notes. The Convertible Senior Notes were issued on November 22, 2013. We received net proceeds of $124.9 million from the sale of the Convertible Senior Notes, after deducting fees and expenses of $6.4 million and $18.7 million related to a capped call transaction. The Convertible Senior Notes are governed by an Indenture, dated as of November 22, 2013, between HPI and U.S. Bank National Association, as trustee. In connection with the Merger, HPI and Horizon Pharma plc executed a supplemental Indenture dated as of September 19, 2014. Pursuant to the supplemental Indenture, HPI remains the obligor of the Convertible Senior Notes and Horizon Pharma plc agreed to fully and unconditionally guaranty the obligations of HPI under the Indenture. The supplemental Indenture also provides that the conversion value of the Convertible Senior Notes will be calculated by reference to the ordinary shares of Horizon Pharma plc, rather than the common stock of HPI, and any shares issuable upon conversion of the Convertible Senior Notes will be settled in ordinary shares of Horizon Pharma plc, rather than shares of the common stock of HPI. In addition, Horizon Pharma plc has assumed the disclosure obligations required by the Indenture.

The Convertible Senior Notes bear interest at a rate of 5.00% per year, payable in arrears on May 15 and November 15 of each year, beginning on May 15, 2014. The Convertible Senior Notes will mature on November 15, 2018, unless earlier repurchased or converted. The Convertible Senior Notes were sold at a price equal to 100% of the principal amount thereof and are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding August 15, 2018 only under certain conditions. On or after August 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date for the Convertible Senior Notes, holders will be able to convert their Convertible Senior Notes at their option at the conversion rate then in effect at any time, regardless of these conditions. Subject to certain limitations, HPI may settle conversions of the Convertible Senior Notes by paying or delivering, as the case may be, cash, our ordinary shares or a combination of cash and our ordinary shares, at HPI’s election. If we undergo a fundamental change prior to the maturity date of the Convertible Senior Notes, the holders may require HPI to repurchase for cash all or any portion of their Convertible Senior Notes at a price equal to 100% of the principal amount of the Convertible Senior Notes to be repurchased, plus accrued and unpaid interest.

The conversion rate for the Convertible Senior Notes was initially 186.4280 ordinary shares per $1,000 principal amount of Convertible Senior Notes (equivalent to an initial conversion price of approximately $5.36 per ordinary share). The conversion rate of the Convertible Senior Notes, and the corresponding conversion price, is subject to adjustment for certain events, but will not be adjusted for accrued and unpaid interest.

On September 23, 2014, the counterparties to the certain capped call transactions we entered into in connection with the Convertible Senior Notes exercised their right to terminate the capped call transactions following the Merger because we became a non-U.S. based entity. In connection with such termination, we received $14.0 million comprised of both $9.4 million in cash and 384,366 of our ordinary shares which were valued at $4.6 million, based on the closing share price of September 22, 2014 of $11.93 per share. We recorded the receipt of the ordinary shares as treasury shares. In addition, in connection with the termination of the capped call transactions, one counterparty and/or their affiliates unwound various hedging transactions with respect to the Company’s ordinary shares.

In the fourth quarter of 2014, we entered into separate, privately-negotiated conversion agreements with certain holders of the Convertible Senior Notes. Under the conversion agreements, the holders agreed to convert an aggregate principal amount of $89.0 million of Convertible Senior Notes held by them and we agreed to settle such conversions by issuing 16,594,793 ordinary shares. In addition, pursuant to the conversion agreements, we made an aggregate cash payment of $16.7 million to the holders for additional exchange consideration and $1.7 million in accrued and unpaid interest, and recognized a non-cash charge of $11.7 million related to the extinguishment of debt as a result of the note conversions. As of December 31, 2014, $61.0 million in aggregate principal amount of the Convertible Senior Notes remained outstanding.
During the year ended December 31, 2014, we received proceeds of $38.5 million in connection with our issuance of an aggregate of 8,990,120 of our ordinary shares upon the exercise of warrants. Additionally, we issued an aggregate of 864,780 ordinary shares in connection with the exercise of stock options and vesting of restricted stock units and received $1.6 million in proceeds in connection with the exercise of stock options, and received proceeds of $1.7 million upon the issuance of 536,543 ordinary shares through our employee stock purchase program.

We are required to maintain compliance with applicable Swiss laws with respect to our Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. We review on a regular basis whether Horizon Pharma AG is overindebted. As of December 31, 2014, Horizon Pharma AG was not overindebted. However, Horizon Pharma AG has previously been overindebted, including at December 31, 2013. We will continue to monitor and review Horizon Pharma AG’s financial position and, as necessary, will address any overindebtedness until such time as Horizon Pharma AG generates positive income at a statutory level, which could require us to have cash at Horizon Pharma AG in excess of its near-term operating needs and could affect our ability to have sufficient cash to meet the near-term operating needs of our other operating subsidiaries. As of December 31, 2014 and 2013, Horizon Pharma AG had cash and cash equivalents of $3.0 million and $3.7 million, respectively. Based upon the cash and cash equivalents held by Horizon Pharma AG as of December 31, 2014 and 2013, we do not expect that our financial position or results of operations will be materially affected by any need to address overindebtedness at Horizon Pharma AG. To date, the overindebtedness of Horizon Pharma AG has not resulted in the need to divert material cash resources from our other operating subsidiaries.

The following table provides a summary of our cash position and cash flows for the years ended December 31, 2014, 2013 and 2012, as follows (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>For the Years Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2014</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$218,807</td>
</tr>
<tr>
<td>Cash provided by (used in):</td>
<td></td>
</tr>
<tr>
<td>Operating activities</td>
<td>27,549</td>
</tr>
<tr>
<td>Investing activities</td>
<td>(227,720)</td>
</tr>
<tr>
<td>Financing activities</td>
<td>338,285</td>
</tr>
</tbody>
</table>

**Net Cash Provided by (Used in) Operating Activities**

During the years ended December 31, 2014, 2013 and 2012, net cash provided by (used in) operating activities was $27.5 million, ($54.3 million) and ($76.6 million), respectively. The increase in net cash provided by operating activities during 2014 compared to 2013 was primarily attributable to higher cash flow from net product sales, partially offset by higher cash outlays for related expenses. Cash provided by operating activities during 2014 was negatively impacted by $51.7 million in transaction costs related to the Merger, the PENNSAID 2% acquisition, and the secondary offering of ordinary shares by certain stockholders in November 2014, and $16.7 million of cash payments related to induced debt conversions.

The decrease in net cash used in operating activities during 2013 compared to 2012 was primarily attributable to an increase in cash flows associated with higher product sales and gross margins of DUEXIS and RAYOS during the year ended December 31, 2013, which was partially offset by additional cash used in operating activities related to increases in our working capital requirements, such as for accounts receivable and inventories due to our increased product sales.

Net cash used in operating activities during 2012 was primarily attributable to staffing our sales and marketing organization and expenses related to our product launches of DUEXIS and RAYOS. Additionally, cash used in operating activities during 2012 was for interest payments made on our Secured Senior Loan, additional staffing of support and administrative functions and for working capital purposes.
Net Cash Used in Investing Activities

During the years ended December 31, 2014, 2013 and 2012, net cash used in investing activities was $227.7 million, $36.1 million and $1.4 million, respectively. The increase in net cash used in investing activities during 2014 was primarily associated with the net cash paid for the acquisition of Vidara of $179.2 million and the acquisition of PENNSAID 2% of $45.0 million.

Net cash used in investing activities during 2013 was primarily attributable to our asset purchase of U.S. rights to VIMOVO for $35.0 million from AstraZeneca in November 2013. Additionally, $1.2 million of cash used in investing activities in 2013 was used for capital expenditures related to computer hardware and equipment purchases for the additional staffing of our sales function.

Net cash used in investing activities during 2012 was primarily attributable to capital expenditures for computer hardware and equipment to support our sales and administrative functions.

Net Cash Provided by Financing Activities

During the years ended December 31, 2014, 2013 and 2012, net cash provided by financing activities was $338.3 million, $66.7 million and $164.3 million, respectively. The increase in net cash provided by financing activities during 2014 was primarily attributable to $300.0 million of proceeds received under the Senior Secured Credit Facility in connection with the Merger in September 2014, net of $13.0 million of original issue discount and deferred financing fees. In addition, during 2014, we received proceeds of $38.5 million in connection with the exercise of warrants to purchase 8,990,120 ordinary shares, and received $9.4 million of cash proceeds from the settlement of the capped call termination in September 2014.

Net cash provided by financing activities in 2013 was primarily attributable to proceeds from the Convertible Senior Notes, net of issuance costs, partially offset by principal debt payments and the extinguishment of our Senior Secured Loan. In connection with our acquisition of the U.S. rights to VIMOVO, we issued $150.0 million aggregate principal amount of Convertible Senior Notes and received net proceeds of $143.6 million from the sale of the Convertible Senior Notes, after deducting fees and expenses of approximately $6.4 million. In addition, we used $18.7 million of the net proceeds to purchase capped calls and used $64.8 million of the net proceeds to repay all obligations under our Senior Secured Loan.

During the year ended December 31, 2013, we sold 2,448,575 shares of HPI common stock through at-the-market offerings for gross proceeds of $6.2 million and net proceeds of $6.0 million, after $0.2 million in commissions and other issuance costs.

Net cash provided by financing activities in 2012 was primarily the result of our debt refinancing and the equity offerings we completed. In February 2012, we entered into our $60.0 million Senior Secured Loan with a group of institutional lenders. As part of the closing of the Senior Secured Loan, we repaid outstanding principal under previous borrowings totaling $19.8 million. In March 2012, we received gross proceeds of $50.8 million and net proceeds of $47.5 million, after deducting $3.3 million in issuance costs, from the sale of 14,033,829 shares of HPI common stock and warrants to purchase an aggregate of 3,508,448 shares of HPI common stock to certain institutional and accredited investors in a private equity placement. In September 2012, we received gross proceeds of $86.2 million and net proceeds of $80.6 million after deducting $5.6 million in issuance costs from the sale of 24,638,750 shares of HPI common stock and warrants to purchase an aggregate of 12,319,375 shares of HPI common stock in a public offering.
### Contractual Obligations

As of December 31, 2014, minimum future cash payments due under contractual obligations, including, among others, our Convertible Senior Notes, minimum purchase agreements and non-cancelable operating lease agreements, were as follows (in thousands):

<table>
<thead>
<tr>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Debt agreements(1)</td>
<td>$30,403</td>
<td>$30,499</td>
<td>$30,424</td>
<td>$91,410</td>
<td>$320,550</td>
<td>$</td>
<td>$503,287</td>
</tr>
<tr>
<td>Purchase commitments(2)</td>
<td>13,578</td>
<td>4,619</td>
<td>4,619</td>
<td>3,527</td>
<td>3,527</td>
<td>3,527</td>
<td>33,397</td>
</tr>
<tr>
<td>Operating lease obligations(3)</td>
<td>1,581</td>
<td>1,624</td>
<td>1,538</td>
<td>1,104</td>
<td>558</td>
<td>5,484</td>
<td>11,889</td>
</tr>
<tr>
<td>Total contractual cash obligations</td>
<td>$45,562</td>
<td>$36,743</td>
<td>$36,581</td>
<td>$96,042</td>
<td>$324,635</td>
<td>$9,011</td>
<td>$548,573</td>
</tr>
</tbody>
</table>

(1) Represents the minimum contractual obligation due under the following debt agreements:
- Convertible Senior Notes, which includes quarterly interest payments and repayment of the Convertible Senior Notes principal in November 2018. The principal balance of the Convertible Senior Notes at December 31, 2014 was $61.0 million.
- $300.0 million Senior Secured Credit Facility, which includes quarterly interest payments and repayment of the principal in September 2019.

(2) These amounts reflect the following purchase commitments with our third party manufacturers:
- Minimum purchase commitment for RAYOS/LODOTRA tablets from Jagotec through December 31, 2017 (the end of the minimum term), which is the firm commitment term under the contract.
- Purchase commitment for final packaged DUEXIS tablets from sanofi-aventis U.S. through March 2015.
- Minimum purchase commitment for VIMOVO tablets from Patheon through April 2015.
- Minimum annual order quantities required to be placed with Boehringer Ingelheim for final packaged ACTIMMUNE through July 2020.
- Purchase commitment for final packaged PENNSAID 2% from Nuvo through April 2015.

(3) These amounts reflect payments due under our operating leases, which are principally for our facilities. We occupy approximately 10,300 square feet of office space in our headquarters in Dublin, Ireland under a lease that expires on November 4, 2029. We also occupy approximately 50,500 square feet of office space in Deerfield, Illinois under lease agreements that expire in June 30, 2018, approximately 5,000 square feet of office space in Mannheim, Germany under a lease that expires on December 31, 2016, approximately 3,200 square feet of office space in Reinach, Switzerland under a lease that expires on May 31, 2015 and approximately 6,200 square feet of office space in Roswell, Georgia under a lease that expires on October 31, 2018.

In addition to the obligations set out in the above table, we have assumed material obligations to pay royalties to certain third parties on net sales of VIMOVO as a result of the acquisition of the U.S. rights to VIMOVO from AstraZeneca in November 2013 and ACTIMMUNE as result of the Merger.

Under the Pozen license agreement, we are required to pay Pozen a flat 10% royalty on net sales of VIMOVO and such other products sold by us, our affiliates or sublicensees during the royalty term, subject to minimum annual royalty obligations of $5.0 million in 2014 and $7.5 million each year thereafter, which minimum royalty obligations will continue for each year during which one of Pozen’s patents covers such products in the United States and there are no competing products in the United States. The royalty rate may be reduced to a mid-single digit royalty rate as a result of loss of market share to competing products. Our obligation
to pay royalties to Pozen will expire upon the later of (a) expiration of the last-to-expire of certain patents covering such products in the United States, and (b) ten years after the first commercial sale of such products in the United States. In addition, we are obligated to reimburse Pozen for costs, including attorneys’ fees, incurred by Pozen in connection with VIMOVO patent litigation moving forward, subject to agreed caps.

Under the terms of the license agreement with Genentech Inc., or Genentech, which was the original developer of ACTIMMUNE, we are or were obligated to pay royalties to Genentech on our net sales of ACTIMMUNE as follows:

- Through November 25, 2014, we were obligated to pay a royalty of 45% of the first $3.7 million in net sales achieved in a calendar year, and 10% on all additional net sales in that year;
- For the period from November 26, 2014 through May 5, 2018, the royalty payments will be reduced to a 20%-30% range for the first tier in net sales and in the 1-9% range for the second tier; and
- From May 6, 2018 and for so long as we continue to commercially sell ACTIMMUNE, we will be obligated to pay an annual royalty in the low single digits as a percentage of annual net sales.

Under the terms of an agreement with Connectics Corporation (which was the predecessor parent company to InterMune and is now part of GlaxoSmithKline), or Connectics, we are obligated to pay royalties to Connectics on our net sales of ACTIMMUNE as follows:

- 0.25% of net sales of ACTIMMUNE, rising to 0.5% once cumulative net sales of ACTIMMUNE in the United States surpass $1.0 billion; and
- In the event we develop and receive regulatory approval for ACTIMMUNE in the indication of scleroderma, we will be obligated to pay a royalty of 4% on all net sales of ACTIMMUNE recorded for use in that indication.

As of December 31, 2014, cumulative net sales of ACTIMMUNE in the United States were $25.3 million.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities, other than the indemnification agreements discussed in Note 14, “Commitments and Contingencies” in the notes to our condensed consolidated financial statements included in this report.

Critical Accounting Policies and Significant Judgments and Estimates

The methods, estimates and judgments that we use in applying our critical accounting policies have a significant impact on the results that we report in our financial statements. Some of our accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates regarding matters that are inherently uncertain.

We have identified the accounting policies and estimates listed below as those that we believe require management’s most subjective and complex judgments in estimating the effect of inherent uncertainties. This section should also be read in conjunction with Note 2, “Summary of Significant Accounting Policies,” in the notes to our condensed consolidated financial statements included in this report, which includes a discussion of these and other significant accounting policies.

Revenue Recognition

Revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectability
is reasonably assured. Some of our agreements contain multiple elements and in accordance with these agreements, we may be eligible for upfront license fees, marketing or commercial milestones and payment for product deliveries.

Revenue from product deliveries

We recognize revenue from the delivery of our products when delivery has occurred, title has transferred, the selling price is fixed or determinable, the right of return no longer exists (which is the earlier of product being dispensed through patient prescriptions or the expiration of the right of return) or product returns can be reasonably estimated, collectability is reasonably assured and we have no further performance obligations. Due to our ability to reasonably estimate and determine allowances for product returns, rebates and discounts based on our own internal data for DUEXIS and RAYOS or data relating to prior sales of VIMOVO and ACTIMMUNE received in connection with the acquisition of those products, we recognize revenue at the point of sale to wholesale pharmaceutical distributors and retail chains for all currently distributed products.

Revenue from upfront license fees

We recognize revenues from the receipt of non-refundable, upfront license fees. In situations where the licensee is able to obtain stand-alone value from the license and no further performance obligations exist on our part, revenues are recognized on the earlier of when payments are received or collection is assured. Where continuing involvement by us is required in the form of technology transfer, product manufacturing or technical support, revenues are deferred and recognized over the term of the agreement.

Revenue from milestone receipts

Milestone payments are recognized as revenue based on achievement of the associated milestones, as defined in the relevant agreements. Revenue from a milestone achievement is recognized when earned, as evidenced by acknowledgment from our partner, provided that (1) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, (2) the milestone represents the culmination of an earnings process and (3) the milestone payment is non-refundable. If any of these criteria are not met, revenue from the milestone achievement is recognized over the remaining minimum period of our performance obligations under the agreement.

Contractual Allowances

Product Sales Discounts and Allowances

We record allowances for product returns, rebates and discounts at the time of sale to wholesale pharmaceutical distributors and national and regional retail chains. We are also required to make significant judgments and estimates in determining some of these allowances. If actual results differ from our estimates, we will be required to make adjustments to these allowances in the future.

Product Launch Discounts

We have offered additional discounts to wholesale distributors for product purchased at the time of product launch. We have recorded these discounts as an allowance against accounts receivable and a reduction of revenue when orders were placed.

Customer Rebates

We participate in certain commercial rebate programs. Under these rebate programs, we pay a rebate to the commercial entity or third-party administrator of the program. We accrue estimated rebates based on contract prices, estimated percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel and record the rebate as a reduction of revenue.
Distribution Service Fees

We include distribution service fees paid to our wholesalers for distribution and inventory management services as a reduction to revenue. We accrue estimated fees based on contractually determined amounts, typically as a percentage of revenue, as a reduction of revenue.

Co-Pay Assistance

We offer discount card and other programs such as our PME program to patients under which the patient receives a discount on his or her prescription. In certain circumstances when a patient’s prescription is rejected by a managed care vendor, we will pay for the full cost of the prescription. We reimburse pharmacies for this discount through third-party vendors. We accrue estimated costs for co-pay assistance based on contract prices, estimated percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel and record the rebate as a reduction of revenue. We record the total amount of estimated discounts for sales recorded in the period as a reduction of revenue.

Sales Returns

Consistent with industry practice, we maintain a return policy that allows customers to return product within a specified period prior to and subsequent to the product expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date and up to one year after its expiration date. The right of return expires on the earlier of one year after the product expiration date or the time that the product is dispensed to the patient. The majority of our product returns are the result of product dating, which falls within the range set by our policy, and are settled through the issuance of a credit to the customer. Our estimate of the provision for returns is based upon our historical experience with actual returns, which is applied to the level of sales for the period that corresponds to the period during which our customer may return product. This period is known to us based on the shelf lives of our products at the time of shipment. We record sales returns as an allowance against accounts receivable and a reduction of revenue.

Prompt Pay Discounts

As an incentive for prompt payment, we offer a 2% cash discount to customers. We expect that all customers will comply with the contractual terms to earn the discount. We record the discount as an allowance against accounts receivable and a reduction of revenue.

Government Rebates and Chargebacks

Government Rebates

We participate in certain federal government rebate programs, such as Medicare and Medicaid. We accrue estimated rebates based on estimated percentages of product sold to qualified patients, estimated rebate percentages and estimated levels of inventory in the distribution channel that will be sold to qualified patients and record the rebates as a reduction of revenue.

Government Chargebacks

We provide discounts to federal government qualified entities with whom we have contracted. These federal entities purchase products from the wholesale pharmaceutical distributors at a discounted price, and the wholesale pharmaceutical distributors then charge back to us the difference between the current retail price and the contracted price that the federal entities paid for the product. We accrue estimated chargebacks based on contract prices and sell-through sales data obtained from third party information and record the chargeback as a reduction of revenue.
The following table summarizes our customer-related accruals and allowances as of December 31, 2014 and 2013 (in thousands):

### Customer-Related Accruals and Allowances

<table>
<thead>
<tr>
<th></th>
<th>Contractual Allowances</th>
<th>Government Rebates and Chargebacks</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at December 31, 2012</td>
<td>$2,234</td>
<td>$321</td>
<td>$2,555</td>
</tr>
<tr>
<td>Current provisions relating to sales in current year</td>
<td>21,799</td>
<td>3,909</td>
<td>25,708</td>
</tr>
<tr>
<td>Adjustments relating to prior year sales</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Payments relating to sales in current year</td>
<td>(16,422)</td>
<td>(2,785)</td>
<td>(19,207)</td>
</tr>
<tr>
<td>Payments relating to sales in prior years</td>
<td>(895)</td>
<td>(38)</td>
<td>(933)</td>
</tr>
<tr>
<td>Balance at December 31, 2013</td>
<td>$ 6,716</td>
<td>$1,407</td>
<td>$8,123</td>
</tr>
<tr>
<td>Current provisions relating to sales in current year</td>
<td>242,091</td>
<td>45,301</td>
<td>287,392</td>
</tr>
<tr>
<td>Adjustments relating to prior year sales</td>
<td>(1,770)</td>
<td>—</td>
<td>(1,770)</td>
</tr>
<tr>
<td>Payments relating to sales in current year</td>
<td>(181,380)</td>
<td>(38,880)</td>
<td>(220,260)</td>
</tr>
<tr>
<td>Payments relating to sales in prior years</td>
<td>(4,842)</td>
<td>(1,307)</td>
<td>(6,149)</td>
</tr>
<tr>
<td>Vidara Acquisition on September 18, 2014</td>
<td>472</td>
<td>13,528</td>
<td>14,000</td>
</tr>
<tr>
<td>Balance at December 31, 2014 (1)</td>
<td>$61,287</td>
<td>$20,049</td>
<td>$81,336</td>
</tr>
</tbody>
</table>

(1) The balance includes $5,221 of unpaid contractual allowance invoices recorded in accounts payable.

### Cost of Goods Sold

We recognize cost of goods sold in connection with our sales of ACTIMMUNE, DUEXIS, LODOTRA, RAYOS and VIMOVO.

Cost of goods sold for ACTIMMUNE includes all costs directly related to the acquisition of ACTIMMUNE from our third-party manufacturer, Boehringer Ingelheim, including freight charges and other direct expenses such as insurance and amortization of intellectual property, royalty accretion expense and any changes in estimate associated with the contingent royalty liability as described in the accrued contingent royalty accounting policy below.

Cost of goods sold for DUEXIS includes all costs directly related to the purchase of product from our third-party manufacturers, including freight charges and costs of distribution service fees.

Cost of goods sold for LODOTRA includes raw material costs, costs associated with third parties who manufacture LODOTRA for us, supply chain costs, amortization of developed technology, royalty payments to third parties for the use of certain licensed patents and applicable taxes.

Cost of goods sold for RAYOS includes all costs directly related to the purchase of product from our third-party manufacturers, including freight charges and costs of distribution, amortization of developed technology, royalty payments to third parties for the use of certain licensed patents and applicable taxes.

Cost of goods sold for VIMOVO includes all costs directly related to the acquisition of product from AstraZeneca and/or a third-party manufacturer, amortization of intellectual property, royalty accretion expense and any changes in estimate associated with the contingent royalty liability as described in the accrued contingent royalty accounting policy below.

### Intangible Assets

Definite-lived intangible assets are amortized over their estimated useful lives. We review our intangible assets when events or circumstances may indicate that the carrying value of these assets exceeds their fair value.
We measure fair value based on the estimated future discounted cash flows associated with our assets in addition to other assumptions and projections that we deem to be reasonable and supportable. The estimated useful lives for all identified intangible assets that are subject to amortization were as follows as of December 31, 2014:

<table>
<thead>
<tr>
<th>Intangible Asset</th>
<th>Estimated Useful Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTIMMUNE developed technology</td>
<td>13 years</td>
</tr>
<tr>
<td>LODOTRA and RAYOS developed technology</td>
<td>12 Years</td>
</tr>
<tr>
<td>PENNSAID 2% developed technology</td>
<td>6 Years</td>
</tr>
<tr>
<td>VIMOVO intellectual property</td>
<td>5 Years</td>
</tr>
<tr>
<td>Customer relationships</td>
<td>10 years</td>
</tr>
</tbody>
</table>

Indefinite-lived intangible assets consist of capitalized in-process research and development, or IPR&D. IPR&D assets represent capitalized incomplete research projects that we acquired through business combinations. Such assets are initially measured at their acquisition date fair values and are tested for impairment, until completion or abandonment of R&D efforts associated with the projects. An IPR&D asset is considered abandoned when R&D efforts associated with the asset have ceased, and there are no plans to sell or license the asset or derive value from the asset. At that point, the asset is considered to be disposed of and is written off. Upon successful completion of each project, we will make a determination about the then remaining useful life of the intangible asset and begin amortization. We test our indefinite-lived intangibles, including IPR&D assets, for impairment annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired.

**Fair Value of Financial Instruments**

The carrying amounts of our financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses, approximate their fair values due to their short maturities. At December 31, 2013 and at the final measurement on June 27, 2014, the estimated fair value of our derivative liability related to the convertible portion of our 5.00% Convertible Senior Notes due 2018, or Convertible Senior Notes, was derived utilizing the binomial lattice approach for the valuation of convertible instruments. Assumptions used in the calculation included, among others, determining the appropriate credit spread using benchmarking analysis and solving for the implied credit spread, calculating the fair value of the stock component using a discounted risk free rate and borrowing cost and calculating the fair value of the note component using a discounted credit adjusted discount rate. Based on the assumptions used to determine the fair value of the derivative liability associated with the Convertible Senior Notes, we concluded that these inputs were Level 3 inputs.

**Business Combinations**

We account for business combinations in accordance with the pronouncement guidance in ASC 805, Business Combinations, in which acquired assets and liabilities are measured at their respective estimated fair values as of the acquisition date. We may be required, as in the case of intangible assets or contingent royalties, to determine the fair value associated with these amounts by estimating the fair value using an income approach under the discounted cash flow method, which may include revenue projections and other assumptions made by us to determine the fair value. During the year ended December 31, 2014, we recorded a bargain purchase gain of $22.2 million in connection with the Merger, representing the excess of the estimated fair values of net assets acquired over the acquisition consideration paid.

**Provision for Income Taxes**

We account for income taxes based upon an asset and liability approach. Deferred tax assets and liabilities represent the future tax consequences of the differences between the financial statement carrying amounts of assets and liabilities versus the tax basis of assets and liabilities. Under this method, deferred tax assets are...
recognized for deductible temporary differences, and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The impact of tax rate changes on deferred tax assets and liabilities is recognized in the year that the change is enacted. We also account for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on an income tax return.

**Stock-Based Compensation**

We account for employee stock-based compensation by measuring and recognizing compensation expense for all stock-based payments based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee’s requisite service period, which is generally the vesting period. We estimate the fair value of our share-based awards to employees using the Black-Scholes option pricing model. The Black-Scholes model requires the input of subjective assumptions, including the expected stock price, volatility, risk-free interest rate, the calculation of expected term and the fair value of the underlying ordinary shares on the date of grant, among other inputs.

We also account for stock options issued to non-employees based on the stock options’ estimated fair value determined using the Black-Scholes option pricing model. The fair value of equity awards granted to non-employees are re-measured at each reporting date, and the resulting change in the fair value associated with awards, if any, is recognized as a corresponding increase or reduction to stock-based compensation during the period.

**Accrued Contingent Royalties**

Our accrued contingent royalties consist of the contingent royalty obligations assumed by us related to our acquisitions of the U.S. rights to VIMOVO and Vidara (related to ACTIMMUNE). At the time of each acquisition, we assigned a fair value to the liability for royalties. The royalty liability was based on anticipated revenue streams utilizing the income approach under the discounted cash flow method. The estimated liability for royalties is increased over time to reflect the change in its present value, and accretion expense is recorded as part of cost of goods sold. We evaluate the adequacy of the estimated contingent royalty liability at least annually, or whenever events or changes in circumstances indicate that an evaluation of the estimate is necessary. As part of any evaluation, we adjust the carrying value of the liability to the present value of the revised estimated cash flows using the original discount rate.

Any decrease or increase to the liability is recorded as an increase or reduction in cost of goods sold. The royalty liability is included in current and long-term accrued royalties on the consolidated balance sheets.

**New Accounting Pronouncements Impacting Critical Accounting Policies**

Refer to Note 2, “Summary of Significant Accounting Policies,” in the notes to our condensed consolidated financial statements included in this report, which includes a discussion of the new accounting pronouncements impacting critical accounting policies.

**Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

We are exposed to various market risks, which include potential losses arising from adverse changes in market rates and prices, such as interest rates and foreign exchange fluctuations. We do not enter into derivatives or other financial instruments for trading or speculative purposes.

**Interest Rate Risk.** We are subject to interest rate fluctuation exposure through our borrowings under the Senior Secured Credit Facility and our investment in money market accounts which bear a variable interest rate.
Borrowings under the Senior Secured Credit Facility bear interest, at our option, at a rate equal to either the London Inter-Bank Offer Rate, or LIBOR, plus an applicable margin of 8.0% per annum (subject to a 1.0% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 7.0% per annum. Since drawing the full $300.0 million available in September 2014, our borrowings have been based on the LIBOR. Since current LIBOR rates are below the 1.0% LIBOR floor, the interest rate on our borrowings has been 9.0% per annum. An increase in the LIBOR of 100 basis points above the 1.0% LIBOR floor would increase our interest expense by $3.0 million per year.

The goals of our investment policy are associated with the preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. To achieve our goal of maximizing income without assuming significant market risk, we maintain our excess cash and cash equivalents in money market funds. Because of the short-term maturities of our cash equivalents, we do not believe that a decrease in interest rates would have any material negative impact on the fair value of our cash equivalents.

**Foreign Currency Risk.** Our purchase cost of ACTIMMUNE under our contract with Boehringer Ingelheim as well as our sales contracts relating to LODOTRA are principally denominated in Euros and are subject to significant foreign currency risk. We also incur certain operating expenses in currencies other than the U.S. dollar in relation to our Ireland operations and foreign subsidiaries, including Horizon Pharma AG; therefore, we are subject to volatility in cash flows due to fluctuations in foreign currency exchange rates, particularly changes in the Euro. To date, we have not entered into any hedging contracts since exchange rate fluctuations have had minimal impact on our results of operations and cash flows.

**Inflation Risk.** We do not believe that inflation has had a material impact on our business or results of operations during the periods for which the condensed consolidated financial statements are presented in this report.

**Credit Risk.** Historically, our accounts receivable balances have been highly concentrated with a select number of customers, consisting primarily of large wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. For the year ended December 31, 2014, our top five customers, American Specialty Pharmacy, Inc., AmerisourceBergen, Cardinal Health, Inc., McKesson Corporation and Rochester Drug Company accounted for approximately 86% of total consolidated gross sales. For the year ended December 31, 2013, our top five customers, AmerisourceBergen, Cardinal Health, Inc., McKesson Corporation, Mundipharma and Rochester Drug Company, accounted for approximately 89% of total consolidated gross sales.

In addition, five customers, American Specialty Pharmacy, Inc., AmerisourceBergen, Cardinal Health, Inc., McKesson Corporation and Rochester Drug accounted for approximately 80% of the Company’s total outstanding accounts receivable balances at December 31, 2014. As of December 31, 2013, AmerisourceBergen, Cardinal Health, Inc., Halsted Pharmacy, McKesson Corporation and Rochester Drug Company, accounted for approximately 85% of our total outstanding accounts receivable balances. Historically, we have not experienced any losses related to our accounts receivable balances.

**Item 8. Financial Statements and Supplementary Data**

The financial information required by Item 8 is contained in Part IV, Item 15 of this Annual Report on Form 10-K.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.
Item 9A. Controls and Procedures
Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of our “disclosure controls and procedures” (as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act), have concluded that, as of December 31, 2014, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer’s management, including its principal executive officer or officers and principal financial officer or officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide reasonable assurance to management and our board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control – Integrated Framework (2013). Management’s assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on management’s assessment, management believes that, as of December 31, 2014, our internal control over financial reporting was effective based on those criteria.

Management’s assessment of internal control over financial reporting as of December 31, 2014, excluded Vidara’s internal controls over financial reporting because Vidara was acquired by us in a reverse acquisition under the acquisition method of accounting for business combination in September 2014. Vidara represented approximately 4% and 9% of our total assets and total net sales, respectively, of the related consolidated financial statement amounts, for the period ended December 31, 2014.

The effectiveness of our internal control over financial reporting as of December 31, 2014 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Changes in Internal Control Over Financial Reporting

As discussed above, on September 19, 2014, a wholly-owned subsidiary of Horizon Pharma plc (formerly known as Vidara Therapeutics International Public Limited Company) merged with and into HPI, with HPI surviving the Merger and becoming a wholly-owned subsidiary of Horizon Pharma plc. HPI is treated as the acquiring company in the Merger for accounting purposes, and the Merger was accounted for as a reverse acquisition under the acquisition method of accounting for business combinations. As a result, the historical financial statements of Horizon Pharma plc reflect the financial position, results of operations and cash flows of HPI only. Following the Merger, the financial statements of the current period reflect the financial position, results of operations and cash flows of Horizon Pharma plc. The results of operations of the acquired Vidara
business are included in the results of operations of Horizon Pharma plc beginning on September 19, 2014. Also, as a result of the Merger, the internal control over financial reporting utilized by HPI prior to the Merger became the internal control over financial reporting of our company, and we are currently in the process of evaluating and integrating Vidara’s historical internal controls over financial reporting with ours.

During the year ended December 31, 2014, other than continuing changes to our internal control processes resulting from the Merger as discussed above, there have been no material changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Cash Long Term Incentive Program

As previously disclosed in our Current Report on Form 8-K filed on November 10, 2014, on November 5, 2014 we approved a performance cash bonus program for the members of our executive committee and executive leadership team, including our executive officers. On February 23, 2014, the compensation committee of our board of directors approved the written plan document for such performance cash bonus program, the Horizon Pharma Public Limited Company Cash Long Term Incentive Program, or Cash Bonus Program.

Under the Cash Bonus Program, our executives are provided the opportunity to earn a cash bonus based on our level of attainment of total shareholder return, or TSR, over the designated performance period of November 5, 2014 through May 5, 2015. For such purposes, TSR means the percentage change in the price of our ordinary shares on a compounded annualized basis plus the dollar value of dividends and distributions made or declared divided by the closing price of our ordinary shares on the record date of the dividends and distributions. The Cash Bonus Program also requires that the TSR for the period from November 5, 2014 to November 4, 2017 must be greater than 15%, or the earlier occurrence of a change in control, as a general condition to payment of any amounts under the Cash Bonus Program.

Participants must remain employed by us through November 4, 2017 unless the earlier departure from employment is due to death, disability, termination without cause or a change in control transaction, as such terms are defined in the Cash Bonus Program. Payments under the Cash Bonus Program, if any, will be made after November 4, 2017 unless a change in control occurs prior to such date.

Under the Cash Bonus Program, actual potential payout levels for each of our executive officers under their pre-determined allocations will be based on the applicable TSR level attained during the performance period of November 5, 2014 through May 5, 2015 and are as follows:

<table>
<thead>
<tr>
<th>Designated Participant</th>
<th>15% and &lt; 25%</th>
<th>≤ 25% and &lt; 40%</th>
<th>≤ 40% and &lt; 60%</th>
<th>≤ 60%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walbert, Timothy P.</td>
<td>$1.202</td>
<td>$2.137</td>
<td>$3.205</td>
<td>$4.541</td>
</tr>
<tr>
<td>Sherman, Jeffrey W.</td>
<td>$0.332</td>
<td>$0.589</td>
<td>$0.884</td>
<td>$1.253</td>
</tr>
<tr>
<td>Carey, Robert F.</td>
<td>$0.414</td>
<td>$0.737</td>
<td>$1.105</td>
<td>$1.566</td>
</tr>
<tr>
<td>Moze, Barry J.</td>
<td>$0.332</td>
<td>$0.589</td>
<td>$0.884</td>
<td>$1.253</td>
</tr>
<tr>
<td>Kody, John J.</td>
<td>$0.414</td>
<td>$0.737</td>
<td>$1.105</td>
<td>$1.566</td>
</tr>
<tr>
<td>Hoelscher, Paul W.</td>
<td>$0.414</td>
<td>$0.737</td>
<td>$1.105</td>
<td>$1.566</td>
</tr>
<tr>
<td>Kelly, David</td>
<td>$0.249</td>
<td>$0.442</td>
<td>$0.663</td>
<td>$0.939</td>
</tr>
</tbody>
</table>

(1) All dollar amounts in the table above are in millions. The maximum award for each participant is reflected under the ≤ 60% TSR Level column next to the participant’s name.
PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors and Executive Officers

The information required by this item is incorporated herein by reference from our definitive Proxy Statement to be filed in connection with our 2015 Annual General Meeting of Shareholders, or our 2015 Proxy Statement, which will be filed with the Securities and Exchange Commission within 120 days after December 31, 2014.

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference from our 2015 Proxy Statement.


The information required by this item is incorporated herein by reference from our 2015 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated herein by reference from our 2015 Proxy Statement.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated herein by reference from our 2015 Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report.

1. Financial Statements

The financial statements listed on the Index to Financial Statements F-3 to F-52 are filed as part of this Annual Report on Form 10-K.

2. Financial Statement Schedules

Schedule II – Valuation and Qualifying Accounts and Reserves for each of the three fiscal years ended December 31, 2014, 2013 and 2012. Other financial statement schedules have been omitted because the required information is included in the consolidated financial statements or notes thereto or because they are not applicable or not required.

3. Exhibits

The exhibits listed on the Index to Exhibits are filed as part of this Annual Report on Form 10-K.
SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HORIZON PHARMA PLC

Dated: February 27, 2015

By: /s/ TIMOTHY P. WALBERT
    Timothy P. Walbert
    President, Chief Executive Officer and Chairman of the Board

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Timothy P. Walbert and Paul W. Hoelscher, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<table>
<thead>
<tr>
<th>SIGNATURE</th>
<th>TITLE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>/s/ TIMOTHY P. WALBERT</td>
<td>President, Chief Executive Officer and Chairman of the Board (Principal Executive Officer)</td>
<td>February 27, 2015</td>
</tr>
<tr>
<td>Timothy P. Walbert</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ PAUL W. HOELSCHER</td>
<td>Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)</td>
<td>February 27, 2015</td>
</tr>
<tr>
<td>Paul W. Hoelscher</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ MICHAEL GREY</td>
<td>Director</td>
<td>February 27, 2015</td>
</tr>
<tr>
<td>Michael Grey</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ LIAM DANIEL</td>
<td>Director</td>
<td>February 27, 2015</td>
</tr>
<tr>
<td>Liam Daniel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ JEFF HIMAWAN</td>
<td>Director</td>
<td>February 27, 2015</td>
</tr>
<tr>
<td>Jeff Himawan, Ph.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ VIRINDER NOHRIA</td>
<td>Director</td>
<td>February 27, 2015</td>
</tr>
<tr>
<td>Virinder Nohria, M.D., Ph.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ RONALD PAULI</td>
<td>Director</td>
<td>February 27, 2015</td>
</tr>
<tr>
<td>Ronald Pauli</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ GINO SANTINI</td>
<td>Director</td>
<td>February 27, 2015</td>
</tr>
<tr>
<td>Gino Santini</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ H. THOMAS WATKINS</td>
<td>Director</td>
<td>February 27, 2015</td>
</tr>
<tr>
<td>H. Thomas Watkins</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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**HORIZON PHARMA PLC**

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<th>Page</th>
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<td>Consolidated Balance Sheets as of December 31, 2014 and 2013</td>
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<td>Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2014, 2013 and 2012</td>
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</tr>
<tr>
<td>Consolidated Statements of Shareholders' Equity (Deficit) for the Years Ended December 31, 2014, 2013 and 2012</td>
<td>F-5</td>
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<td>F-7</td>
</tr>
</tbody>
</table>
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Horizon Pharma plc

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of Horizon Pharma plc and its subsidiaries at December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company’s management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management’s Report on Internal Control over Financial Reporting incorporated by reference under Item 9A. Our responsibility is to express opinions on these financial statements, the financial statement schedule and on the Company’s internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As described in Management’s Report on Internal Control over Financial Reporting, management has excluded the internal controls over financial reporting of Vidara Therapeutics International Public Limited Company and its subsidiaries prior to the effective time of the merger on September 19, 2014 (“Vidara”), from its assessment of internal control over financial reporting as of December 31, 2014 because Vidara was acquired by the Company in a reverse acquisition under the acquisition method of accounting for business combination on September 19, 2014. We have also excluded Vidara from our audit of internal control over financial reporting, Vidara’s total assets and total net sales represented approximately 4% and 9%, respectively, of the Company’s related consolidated financial statement amounts as of and for the year ended December 31, 2014.

/s/ PricewaterhouseCoopers LLP
Chicago, Illinois
February 27, 2015

F-2
## HORIZON PHARMA PLC
### CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

<table>
<thead>
<tr>
<th>ASSETS</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CURRENT ASSETS:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$218,807</td>
<td>$80,480</td>
</tr>
<tr>
<td>Restricted cash</td>
<td>738</td>
<td>738</td>
</tr>
<tr>
<td>Accounts receivable, net</td>
<td>73,915</td>
<td>15,958</td>
</tr>
<tr>
<td>Inventories, net</td>
<td>16,865</td>
<td>8,701</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>14,370</td>
<td>4,888</td>
</tr>
<tr>
<td>Deferred tax assets, current</td>
<td>1,530</td>
<td>—</td>
</tr>
<tr>
<td>Total current assets</td>
<td>326,225</td>
<td>110,765</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>7,241</td>
<td>3,780</td>
</tr>
<tr>
<td>Developed technology, net</td>
<td>696,963</td>
<td>131,094</td>
</tr>
<tr>
<td>In-process research and development</td>
<td>66,000</td>
<td>—</td>
</tr>
<tr>
<td>Other intangible assets, net</td>
<td>7,870</td>
<td>—</td>
</tr>
<tr>
<td>Deferred tax assets, net, non-current</td>
<td>18,761</td>
<td>—</td>
</tr>
<tr>
<td>Other assets</td>
<td>11,564</td>
<td>6,957</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td>$1,134,624</td>
<td>$252,596</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LIABILITIES AND SHAREHOLDERS' EQUITY</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CURRENT LIABILITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convertible debt, net</td>
<td>$48,334</td>
<td>$—</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>21,011</td>
<td>9,921</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>46,625</td>
<td>15,926</td>
</tr>
<tr>
<td>Accrued trade discounts and rebates</td>
<td>76,115</td>
<td>8,123</td>
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<tr>
<td>Accrued royalties—current portion</td>
<td>25,325</td>
<td>8,010</td>
</tr>
<tr>
<td>Deferred tax liabilities, net</td>
<td>721</td>
<td>—</td>
</tr>
<tr>
<td>Deferred revenues—current portion</td>
<td>1,261</td>
<td>1,330</td>
</tr>
<tr>
<td>Total current liabilities</td>
<td>219,392</td>
<td>43,310</td>
</tr>
<tr>
<td><strong>LONG-TERM LIABILITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convertible debt, net of current</td>
<td>—</td>
<td>110,762</td>
</tr>
<tr>
<td>Long-term debt, net</td>
<td>297,169</td>
<td>—</td>
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<tr>
<td>Derivative liability</td>
<td>—</td>
<td>109,410</td>
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<tr>
<td>Accrued royalties, net of current</td>
<td>48,887</td>
<td>24,982</td>
</tr>
<tr>
<td>Deferred revenues, net of current</td>
<td>8,144</td>
<td>9,686</td>
</tr>
<tr>
<td>Deferred tax liabilities, net, non-current</td>
<td>19,570</td>
<td>3,362</td>
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<tr>
<td>Other long-term liabilities</td>
<td>1,258</td>
<td>166</td>
</tr>
<tr>
<td>Total long-term liabilities</td>
<td>375,028</td>
<td>258,368</td>
</tr>
<tr>
<td><strong>COMMITMENTS AND CONTINGENCIES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SHAREHOLDERS’ EQUITY:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ordinary shares, $0.0001 nominal value; 300,000,000 shares authorized; 125,425,853 and 66,097,417 shares issued at December 31, 2014 and 2013, respectively, and 124,041,487 and 66,097,417 shares outstanding at December 31, 2014 and 2013, respectively</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treasury stock, 384,366 ordinary shares at December 31, 2014</td>
<td>(4,585)</td>
<td>—</td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td>1,269,858</td>
<td>410,430</td>
</tr>
<tr>
<td>Accumulated other comprehensive loss</td>
<td>(4,363)</td>
<td>(2,403)</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(720,719)</td>
<td>(457,116)</td>
</tr>
<tr>
<td>Total shareholders’ equity (deficit)</td>
<td>540,204</td>
<td>(49,082)</td>
</tr>
<tr>
<td><strong>TOTAL LIABILITIES AND SHAREHOLDERS’ EQUITY</strong></td>
<td>$1,134,624</td>
<td>$252,596</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.

F-3
HORIZON PHARMA PLC
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands, except share data)

For the Years Ended December 31,

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVENUES:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net sales</td>
<td>$296,955</td>
<td>$74,016</td>
<td>$18,844</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>78,253</td>
<td>14,625</td>
<td>11,875</td>
</tr>
<tr>
<td><strong>Gross profit</strong></td>
<td>218,202</td>
<td>59,391</td>
<td>6,969</td>
</tr>
<tr>
<td><strong>OPERATING EXPENSES:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>17,460</td>
<td>10,084</td>
<td>16,837</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>120,276</td>
<td>68,595</td>
<td>49,561</td>
</tr>
<tr>
<td>General and administrative</td>
<td>88,957</td>
<td>23,566</td>
<td>19,444</td>
</tr>
<tr>
<td><strong>Total operating expenses</strong></td>
<td>226,693</td>
<td>102,245</td>
<td>85,842</td>
</tr>
<tr>
<td>Operating loss</td>
<td>(8,491)</td>
<td>(42,854)</td>
<td>(78,873)</td>
</tr>
<tr>
<td><strong>OTHER (EXPENSE) INCOME, NET:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(23,826)</td>
<td>(12,774)</td>
<td>(11,552)</td>
</tr>
<tr>
<td>Foreign exchange (loss) gain</td>
<td>(3,905)</td>
<td>1,206</td>
<td>489</td>
</tr>
<tr>
<td>Loss on derivative fair value</td>
<td>(214,995)</td>
<td>(69,300)</td>
<td>—</td>
</tr>
<tr>
<td>Loss on induced conversion and debt extinguishment</td>
<td>(29,390)</td>
<td>(26,404)</td>
<td>(2,973)</td>
</tr>
<tr>
<td>Bargain purchase gain</td>
<td>22,171</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Other, net</td>
<td>(11,251)</td>
<td>—</td>
<td>(56)</td>
</tr>
<tr>
<td><strong>Total other expense, net</strong></td>
<td>(261,196)</td>
<td>(107,272)</td>
<td>(14,092)</td>
</tr>
<tr>
<td>Loss before benefit for income taxes</td>
<td>(269,687)</td>
<td>(150,126)</td>
<td>(92,965)</td>
</tr>
<tr>
<td><strong>BENEFIT FOR INCOME TAXES</strong></td>
<td>(6,084)</td>
<td>(1,121)</td>
<td>(5,171)</td>
</tr>
<tr>
<td><strong>NET LOSS</strong></td>
<td>$ (263,603)</td>
<td>$ (149,005)</td>
<td>$ (87,794)</td>
</tr>
</tbody>
</table>

**NET LOSS PER ORDINARY SHARE - Basic and diluted**

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreign currency translation adjustments</td>
<td>(1,960)</td>
<td>969</td>
<td>416</td>
</tr>
<tr>
<td>Other comprehensive (loss) income</td>
<td>(1,960)</td>
<td>969</td>
<td>416</td>
</tr>
<tr>
<td><strong>COMPREHENSIVE LOSS</strong></td>
<td>$ (265,563)</td>
<td>$ (148,036)</td>
<td>$ (87,378)</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.

F-4
### CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)

(In thousands, except share data)

<table>
<thead>
<tr>
<th></th>
<th>Ordinary Shares</th>
<th>Treasury Stock</th>
<th>Additional Paid-in Capital</th>
<th>Accumulated Comprehensive Loss</th>
<th>Accumulated Deficit</th>
<th>Total Stockholders' Equity (Deficit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shares</td>
<td>Shares</td>
<td>Amount</td>
<td>Shares</td>
<td>Amount</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Balances at December 31, 2011</td>
<td>19,627,744</td>
<td>2</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>45,912</td>
</tr>
<tr>
<td>Issuance of ordinary shares in conjunction with equity financing offerings, net of underwriting fees and issuance costs</td>
<td>38,672,579</td>
<td>4</td>
<td>—</td>
<td>—</td>
<td>128,075</td>
<td>45,912</td>
</tr>
<tr>
<td>Issuance of ordinary shares in conjunction with vesting of restricted stock units</td>
<td>74,050</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of ordinary shares in conjunction with ESPP purchases</td>
<td>106,955</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>287</td>
<td>—</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>4,661</td>
<td>4,661</td>
</tr>
<tr>
<td>Issuance of ordinary shares in conjunction with warrant exercises</td>
<td>1,990,919</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>154</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of warrants in connection with notes payable</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>9,188</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of ordinary shares in conjunction with notes payable amendment</td>
<td>1,250,000</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>5,075</td>
<td>—</td>
</tr>
<tr>
<td>Currency translation adjustment</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>416</td>
<td>—</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(87,794)</td>
</tr>
<tr>
<td>Balances at December 31, 2012</td>
<td>61,722,247</td>
<td>6</td>
<td>—</td>
<td>—</td>
<td>417,455</td>
<td>(3,372)</td>
</tr>
<tr>
<td>Issuance of ordinary shares in conjunction with ATM equity financing offerings, net of issuance costs</td>
<td>2,448,575</td>
<td>1</td>
<td>—</td>
<td>—</td>
<td>5,997</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of ordinary shares in conjunction with vesting of restricted stock units and stock option exercises</td>
<td>340,029</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>161</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of ordinary shares in conjunction with ESPP purchases</td>
<td>225,820</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>478</td>
<td>—</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>5,014</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of ordinary shares in conjunction with warrant exercises</td>
<td>1,360,746</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Purchase of capped calls</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(18,675)</td>
<td>—</td>
</tr>
<tr>
<td>Currency translation adjustment</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>969</td>
<td>—</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(149,005)</td>
</tr>
<tr>
<td>Balances at December 31, 2013</td>
<td>66,097,417</td>
<td>7</td>
<td>—</td>
<td>—</td>
<td>410,430</td>
<td>(2,403)</td>
</tr>
<tr>
<td>Issuance of ordinary shares in connection with Vidara merger</td>
<td>31,350,000</td>
<td>3</td>
<td>—</td>
<td>—</td>
<td>387,796</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of ordinary shares in conjunction with inducement of convertible notes</td>
<td>16,594,793</td>
<td>2</td>
<td>—</td>
<td>—</td>
<td>78,437</td>
<td>—</td>
</tr>
<tr>
<td>Reclassification of derivative liability</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>324,405</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of ordinary shares in conjunction with vesting of restricted stock units and stock option exercises</td>
<td>864,780</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1,612</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of ordinary shares in conjunction with ESPP purchases</td>
<td>536,543</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1,674</td>
<td>—</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>13,197</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of ordinary shares in conjunction with warrant exercises</td>
<td>8,990,120</td>
<td>1</td>
<td>—</td>
<td>—</td>
<td>38,460</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from capped call transactions</td>
<td>—</td>
<td>—</td>
<td>384,366</td>
<td>(4,585)</td>
<td>13,197</td>
<td>—</td>
</tr>
<tr>
<td>Treasury stock purchase</td>
<td>—</td>
<td>—</td>
<td>7,800</td>
<td>(123)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Treasury stock retirement</td>
<td>(7,800)</td>
<td>—</td>
<td>(7,800)</td>
<td>123</td>
<td>(123)</td>
<td>—</td>
</tr>
<tr>
<td>Currency translation adjustment</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(1,960)</td>
<td>—</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(263,603)</td>
<td>—</td>
</tr>
<tr>
<td>Balances at December 31, 2014</td>
<td>124,425,853</td>
<td>13</td>
<td>384,366</td>
<td>(4,585)</td>
<td>1,269,858</td>
<td>(4,363)</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.

F-5
HORIZON PHARMA PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

For the Years Ended December 31,

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CASH FLOWS FROM OPERATING ACTIVITIES:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$(263,603)</td>
<td>$(149,005)</td>
<td>$(87,794)</td>
</tr>
<tr>
<td>Adjustments to reconcile net loss to net cash provided by (used in) operating activities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remeasurement of VIMOVO and ACTIMMUNE royalty liabilities</td>
<td>10,660</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Depreciation and amortization expense</td>
<td>34,009</td>
<td>9,310</td>
<td>5,338</td>
</tr>
<tr>
<td>Share-based compensation</td>
<td>13,198</td>
<td>5,014</td>
<td>4,266</td>
</tr>
<tr>
<td>Bargain purchase gain</td>
<td>(22,171)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Loss on derivative revaluation</td>
<td>214,995</td>
<td>69,300</td>
<td>—</td>
</tr>
<tr>
<td>Royalty accrual</td>
<td>9,020</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Loss on debt extinguishment</td>
<td>11,709</td>
<td>12,881</td>
<td>—</td>
</tr>
<tr>
<td>Amortization of debt discount and deferred financing costs</td>
<td>9,273</td>
<td>2,225</td>
<td>2,607</td>
</tr>
<tr>
<td>Foreign exchange loss (gain)</td>
<td>3,905</td>
<td>(1,206)</td>
<td>(489)</td>
</tr>
<tr>
<td>Royalty accretion</td>
<td>9,020</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Loss on disposal of assets</td>
<td>3,905</td>
<td>1,206</td>
<td>(489)</td>
</tr>
<tr>
<td>Changes in operating assets and liabilities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts receivable</td>
<td>(46,183)</td>
<td>(12,491)</td>
<td>(1,087)</td>
</tr>
<tr>
<td>Inventories</td>
<td>7,173</td>
<td>(3,426)</td>
<td>(4,022)</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>(9,208)</td>
<td>(1,240)</td>
<td>(543)</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>9,383</td>
<td>3,908</td>
<td>(2,209)</td>
</tr>
<tr>
<td>Accrued trade discounts and rebates</td>
<td>54,090</td>
<td>6,962</td>
<td>7,260</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>(1,270)</td>
<td>980</td>
<td>(208)</td>
</tr>
<tr>
<td>Deferred revenues</td>
<td>(562)</td>
<td>(1,143)</td>
<td>2,616</td>
</tr>
<tr>
<td>Deferred income taxes</td>
<td>(7,516)</td>
<td>(1,186)</td>
<td>(5,206)</td>
</tr>
<tr>
<td>Other non-current assets and liabilities</td>
<td>616</td>
<td>468</td>
<td>581</td>
</tr>
<tr>
<td>Net cash provided by (used in) operating activities</td>
<td>27,549</td>
<td>(54,287)</td>
<td>(76,641)</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM INVESTING ACTIVITIES:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Payments for acquisitions, net of cash acquired</td>
<td>(224,220)</td>
<td>(35,000)</td>
<td>—</td>
</tr>
<tr>
<td>Purchases of property and equipment</td>
<td>(3,500)</td>
<td>(1,198)</td>
<td>(1,336)</td>
</tr>
<tr>
<td>Change in restricted cash</td>
<td>—</td>
<td>63</td>
<td>(50)</td>
</tr>
<tr>
<td>Net cash used in investing activities</td>
<td>(227,720)</td>
<td>(36,135)</td>
<td>(1,386)</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM FINANCING ACTIVITIES:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proceeds from the issuance of debt, net of underwriting fees and issuance costs</td>
<td>286,966</td>
<td>143,998</td>
<td>55,578</td>
</tr>
<tr>
<td>Proceeds from the issuance of ordinary shares in connection with warrant exercises</td>
<td>38,461</td>
<td>—</td>
<td>154</td>
</tr>
<tr>
<td>Proceeds from settlement of capped call transactions</td>
<td>9,385</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from the issuance of ordinary shares through ESPP programs and stock option exercises</td>
<td>3,473</td>
<td>639</td>
<td>287</td>
</tr>
<tr>
<td>Repayment of notes payable</td>
<td>—</td>
<td>(64,844)</td>
<td>(19,788)</td>
</tr>
<tr>
<td>Purchase of capped calls</td>
<td>—</td>
<td>(18,675)</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from the issuance of ordinary shares under an ATM agreement, net of issuance costs</td>
<td>—</td>
<td>5,998</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from equity finance offerings, net of offering costs</td>
<td>—</td>
<td>—</td>
<td>128,077</td>
</tr>
<tr>
<td>Net cash provided by financing activities</td>
<td>338,285</td>
<td>66,716</td>
<td>164,308</td>
</tr>
<tr>
<td>Effect of foreign exchange rate changes on cash</td>
<td>273</td>
<td>99</td>
<td>(196)</td>
</tr>
<tr>
<td><strong>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</strong></td>
<td>138,127</td>
<td>(23,607)</td>
<td>86,121</td>
</tr>
<tr>
<td><strong>CASH AND CASH EQUIVALENTS, BEGINNING OF THE YEAR</strong></td>
<td>30,480</td>
<td>104,087</td>
<td>17,966</td>
</tr>
<tr>
<td><strong>CASH AND CASH EQUIVALENTS, END OF THE YEAR</strong></td>
<td>$ 218,807</td>
<td>$ 80,480</td>
<td>$ 104,087</td>
</tr>
</tbody>
</table>

**Supplemental cash flow information:**

- Cash paid for interest | $14,109 | $ 8,573 | $ 7,354 |
- Cash paid for income taxes | $37 | $ 44 | $ 57 |
- Cash paid for induced conversion and debt extinguishment | $16,690 | $ 12,152 | $ 2,124 |

**Supplemental non-cash flow information:**

- Contingent liabilities assumed in acquisition | $33,600 | $ 32,992 | — |
- Intangible assets acquired in acquisition | $679,100 | $ 67,705 | — |
- Accrued capital expenditures | $1,463 | — | — |
- Conversion of Convertible Senior Notes to ordinary shares | $89,015 | — | — |

The accompanying notes are an integral part of these consolidated financial statements.

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NOTE 1 – BASIS OF PRESENTATION

On September 19, 2014, the businesses of Horizon Pharma, Inc. (“HPI”) and Vidara Therapeutics International Public Limited Company (“Vidara”) were combined in a merger transaction (the “Merger”), accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with HPI treated as the acquiring company in the Merger for accounting purposes. As part of the Merger, a wholly-owned subsidiary of Vidara merged with and into HPI, with HPI surviving the Merger as a wholly-owned subsidiary of Vidara and Vidara changed its name to Horizon Pharma plc (“New Horizon” or the “Company”). Upon the consummation of the Merger, the historical financial statements of HPI became the Company’s historical financial statements. Accordingly, the historical financial statements of HPI are included in the comparative prior periods.

Business Overview

The Company is a specialty biopharmaceutical company focused on improving patients’ lives by identifying, developing, acquiring or in-licensing and commercializing differentiated products that address unmet medical needs. The Company markets a portfolio of products in arthritis, inflammation and orphan diseases. The Company’s U.S. marketed products are ACTIMMUNE® (interferon gamma-1b), DUEXIS® (ibuprofen/famotidine), PENNSAID® (diclofenac sodium topical solution) 2% w/w (“PENNSAID 2%”), RAYOS® (prednisone) delayed-release tablets and VIMOVO® (naproxen/esomeprazole magnesium). The Company developed DUEXIS and RAYOS/LODOTRA®, acquired the U.S. rights to VIMOVO from AstraZeneca AB (“AstraZeneca”) in November 2013, acquired the U.S. rights to ACTIMMUNE as a result of the Merger, and acquired the U.S. rights to PENNSAID 2% from Nuvo Research Inc. (“Nuvo”) in October 2014. The Company markets its products in the United States through a combined field sales force of approximately 375 representatives consisting of approximately 325 primary care sales representatives and 50 sales representatives in its specialty and orphan diseases business areas. The Company’s strategy is to develop, acquire or in-license additional innovative medicines or acquire companies, such as the addition of ACTIMMUNE through the recently-completed Merger and the acquisition of the U.S. rights to PENNSAID 2% from Nuvo.

The Company is a public limited company formed under the laws of Ireland. As a result of the Merger, the Company operates through a number of international and U.S. subsidiaries with principal business purposes to either hold intellectual property assets, perform research and development or manufacturing operations, serve as distributors of the Company’s products, or provide services and financial support to the Company. The Company’s international operations are conducted primarily through HZNP Limited, which is responsible for research and development for ACTIMMUNE and PENNSAID 2%, Horizon Pharma Ireland Limited, which is responsible for manufacturing ACTIMMUNE and PENNSAID 2%, Horizon Pharma AG, a company organized under the laws of Switzerland, along with its wholly-owned subsidiary Horizon Pharma GmbH, a company organized under the laws of Germany, together which are responsible for manufacturing RAYOS/LODOTRA, and for international sales of LODOTRA. The Company’s U.S. operations are conducted primarily through Horizon Pharma USA, Inc. which is responsible for research and development and manufacturing of DUEXIS and VIMOVO, and distribution in the U.S. market of DUEXIS, VIMOVO and RAYOS, and other products the Company may potentially acquire, such as the recently acquired PENNSAID 2%, as well as through HZNP USA Inc. which is responsible for distribution of ACTIMMUNE in the United States. Unless otherwise indicated or the context otherwise requires, references to the “Company”, “New Horizon”, “we”, “us” and “our” refer to Horizon Pharma plc and its consolidated subsidiaries, including its predecessor, HPI. All references to “Vidara” are references to Horizon Pharma plc (formerly known as Vidara Therapeutics International Public Limited Company) and its consolidated subsidiaries.

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prior to the effective time of the Merger on September 19, 2014. The disclosures in this report relating to the pre-Merger business of Horizon Pharma plc, unless noted as being the business of Vidara prior to the Merger, pertain to the business of HPI prior to the Merger.

On April 23, 2011, the U.S. Food and Drug Administration (“FDA”) approved DUEXIS, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis (“RA”), osteoarthritis (“OA”) and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for these indications. The Company began marketing DUEXIS to physicians in December 2011. In June 2012, the Company licensed DUEXIS rights in Latin America to Grünenthal S.A., a private company focused on the promotion of pain products.

The Company’s second approved product in the United States, RAYOS, known as LODOTRA outside the United States, is a proprietary delayed-release formulation of low-dose prednisone, first approved in Europe in March 2009, for the treatment of moderate to severe, active RA in adults, particularly when accompanied by morning stiffness. On July 26, 2012, the FDA approved RAYOS for the treatment of RA, polymyalgia rheumatica (“PMR”), psoriatic arthritis, ankylosing spondylitis (“AS”), asthma and chronic obstructive pulmonary disease and a number of other conditions. The Company is focusing its promotion of RAYOS in the United States on rheumatology indications, including RA and PMR. The Company began marketing RAYOS to a subset of U.S. rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of U.S. rheumatologists and key primary care physicians. LODOTRA is currently marketed outside the United States, excluding Japan and Canada, by the Company’s distribution partner, Mundipharma International Corporation Limited (“Mundipharma”).

On November 18, 2013, the Company entered into agreements with AstraZeneca pursuant to which the Company acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with non-steroidal anti-inflammatory drugs (“NSAIDs”) in the United States. VIMOVO is a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a proton pump inhibitor, layer surrounding the core. VIMOVO was originally developed by Pozen Inc. (“Pozen”) together with AstraZeneca pursuant to an exclusive global collaboration and license agreement under which AstraZeneca and Pozen agreed to co-develop VIMOVO and AstraZeneca obtained exclusive rights to commercialize VIMOVO worldwide. On April 30, 2010, the FDA approved VIMOVO for the relief of the signs and symptoms of OA, RA, and AS and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

Under the asset purchase agreement with AstraZeneca, the Company acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the investigational new drug application (“IND”) and new drug application (“NDA”) for VIMOVO in the United States. VIMOVO in the United States. In addition, AstraZeneca assigned to the Company its amended and restated collaboration and license agreement for the United States with Pozen, pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States. For accounting purposes, the acquisition of the U.S. rights to VIMOVO was treated as a business combination. Collectively, these transactions are referred to as the “VIMOVO Acquisition.”

In December 2013, as a result of its acquisition of the U.S. rights to VIMOVO, the Company began recognizing revenues under the transition agreement with AstraZeneca. The Company announced the availability of Horizon-labeled VIMOVO on January 2, 2014, at which time it also began marketing with its primary care sales force and began direct recording VIMOVO revenue.
On March 18, 2014, the Company, Vidara Therapeutics Holdings LLC, a Delaware limited liability company (“Vidara Holdings”), Vidara, Hamilton Holdings (USA), Inc., a Delaware corporation and an indirect wholly-owned subsidiary of Vidara (“U.S. HoldCo”), and Hamilton Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of U.S. HoldCo (“Merger Sub”), entered into a Transaction Agreement and Plan of Merger (the “Merger Agreement”). Upon consummation of the Merger on September 19, 2014 (the “Closing”), the security holders of HPI (excluding the holders of HPI’s convertible notes) owned approximately 74% of the Company and Vidara Holdings owned approximately 26% of the Company. At the Closing, New Horizon made a cash payment of $210.9 million to Vidara Holdings and $2.7 million to Citibank N.A. as escrow agent under an escrow agreement associated with the Merger.

In connection with the Merger, on June 17, 2014, the Company entered into a senior secured credit facility with certain lenders and Citibank, N.A., as administrative agent and collateral agent, that provided the Company with $300.0 million in financing over a five-year period (the “Senior Secured Credit Facility”). The Company borrowed the full $300.0 million available under the Senior Secured Credit Facility on September 19, 2014 and used a portion of the proceeds to provide the cash payment of $213.6 million for the Merger and to pay certain transaction related expenses, and is using the balance for general corporate purposes.

As a result of the Merger, the Company began marketing ACTIMMUNE, a bioengineered form of interferon gamma-1b, a protein that acts as a biologic response modifier, in the United States. ACTIMMUNE is approved by the FDA for use in children and adults with chronic granulomatous disease (“CGD”) and severe, malignant osteopetrosis (“SMO”). ACTIMMUNE is indicated for reducing the frequency and severity of serious infections associated with CGD and for delaying time to disease progression in patients with SMO. The FDA has agreed to the primary endpoint for a Phase 3 study that will evaluate ACTIMMUNE in the treatment of Friedreich’s Ataxia (“FA”). In February 2015, the Company submitted an IND application and anticipates the Phase 3 clinical study related to FA will begin enrolling patients in the second quarter of 2015.

On October 17, 2014, the Company acquired the U.S. rights to PENNSAID 2% from Nuvo for $45.0 million in cash. PENNSAID 2% is approved in the United States for the treatment of the pain of OA of the knee(s). As part of the acquisition, the Company entered into an eight-year exclusive supply agreement with Nuvo. The Company began marketing PENNSAID 2% in January 2015. In connection with the PENNSAID 2% acquisition, the Company expanded its primary care sales force by 75 additional representatives. Effective January 1, 2015, the Company’s primary care representatives are now marketing DUEXIS, PENNSAID 2% and VIMOVO.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation
The accompanying consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America (“GAAP”) and in accordance with the instructions for Form 10-K and Article 3 of Regulation S-X. The consolidated financial statements include the accounts of the Company and its wholly-owned consolidated subsidiaries.

Principles of Consolidation
The consolidated financial statements include the Company’s accounts and those of its wholly-owned subsidiaries in the United States, Ireland, Bermuda, Luxembourg, Switzerland, Germany and the United Kingdom. All intercompany accounts and transactions have been eliminated. Additionally, certain reclassifications have been made to prior period financial statements to conform to the current period presentation.

During the second quarter of 2014, the Company changed its income statement presentation to present net sales rather than presenting gross sales minus sales discounts and allowances. The revised presentation has no
During the first quarter of 2014, the Company recorded an out of period correction of $1.6 million resulting in a reduction to its distribution service fees related to prior periods. This correction to distribution service fees was recorded as an increase in net sales within the Company’s condensed consolidated statements of comprehensive loss for the year ended December 31, 2014. The Company has evaluated the impact of the reduction in distribution service fees to prior reporting periods and has determined it was immaterial.

**Segment Information**

The Company operates as one segment. Management uses one measure of profitability and does not segment its business for internal reporting.

**Use of Estimates**

The preparation of the accompanying condensed consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**Foreign Currency Translation and Transactions**

The reporting currency of the Company and its subsidiaries is the U.S. dollar.

The U.S. dollar is the functional currency for the Company’s U.S. based businesses and its subsidiaries in Ireland, Bermuda and Luxembourg. Other foreign subsidiaries have the following functional currencies: Switzerland (Euro), Germany (Euro) and U.K. (British Pound). Foreign currency-denominated assets and liabilities of these subsidiaries are translated into U.S. dollars based on exchange rates prevailing at the end of the period, revenues and expenses are translated at average exchange rates prevailing during the corresponding period, and shareholders’ equity (deficit) accounts are translated at historical exchange rates as of the date of any equity transaction. The effects of foreign exchange gains and losses arising from the translation of assets and liabilities of those entities where the functional currency is not the U.S. dollar are included as a component of accumulated other comprehensive income (loss).

Gains and losses resulting from foreign currency translations are reflected within the Company’s results of operations. During the year ended December 31, 2014, the Company recorded a loss from foreign currency translations of $3.9 million, compared to a gain from foreign currency translations during the year ended December 31, 2013 of $1.2 million. The Company does not currently utilize and has not in the past utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

**Revenue Recognition**

Revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectability is reasonably assured. Some of the Company’s agreements contain multiple elements and in accordance with these agreements, the Company may be eligible for upfront license fees, marketing or commercial milestones and payment for product deliveries.

**Revenue from product deliveries**

The Company recognizes revenue from the delivery of its products when delivery has occurred, title has transferred, the selling price is fixed or determinable, collectability is reasonably assured and the Company has
no further performance obligations. In addition, revenue is only recognized when the right of return no longer exists (which is the earlier of the product being dispensed through patient prescriptions or the expiration of the right of return) or when product returns can be reasonably estimated. Due to the Company’s ability to reasonably estimate and determine allowances for product returns, rebates and discounts based on its own internal data for DUEXIS and RAYOS or data relating to prior sales of VIMOVO and ACTIMMUNE received in connection with the acquisition of those products, the Company recognizes revenue at the point of sale to wholesale pharmaceutical distributors and retail chains for all currently distributed products.

Revenue from upfront license fees

The Company recognizes revenues from the receipt of non-refundable, upfront license fees. In situations where the licensee is able to obtain stand-alone value from the license and no further performance obligations exist on the Company’s part, revenues are recognized on the earlier of when payments are received or collection is reasonably assured. Where continuing involvement by the Company is required in the form of technology transfer, product manufacturing or technical support, revenues are deferred and recognized over the term of the agreement.

Revenue from milestone receipts

Milestone payments are recognized as revenue based on achievement of the associated milestones, as defined in the relevant agreements. Revenue from a milestone achievement is recognized when earned, as evidenced by acknowledgment from the Company’s partner, provided that (1) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, (2) the milestone represents the culmination of an earnings process and (3) the milestone payment is non-refundable. If any of these criteria are not met, revenue from the milestone achievement is recognized over the remaining minimum period of the Company’s performance obligations under the agreement.

The Company anticipates revenues will continue to result from distribution, marketing, manufacturing and supply agreements with third parties in Europe and certain Asian, Latin American and other countries with respect to LODOTRA.

Under the manufacturing and supply agreements with Mundipharma Medical Company (“Mundipharma Medical”), Mundipharma Medical agreed to purchase LODOTRA exclusively from the Company at a price based on a specified percentage of the average net selling price (“ANSP”) for sales in a given country, subject to a minimum price. Mundipharma Medical has a nine-month period from purchase date to request an ANSP adjustment. If the ANSP is lower than the actual purchase price, then Mundipharma Medical would receive a price adjustment. Revenue for products sold to Mundipharma Medical is recognized upon delivery at the minimum price, as no contractual right of return exists. The difference between the actual selling price and the minimum price is recorded as deferred revenue until such time as adjustments for product returns, rebates and discounts can be reliably estimated or the nine-month ANSP adjustment period passes, at which time any previously deferred revenue would be recognized as revenue. As of December 31, 2014 and 2013, deferred revenues related to the sale of LODOTRA were $0.7 million and $0.6 million, respectively. Additionally, as of December 31, 2014 and 2013, deferred revenues related to milestone and upfront payments received under existing agreements were $7.1 million and $8.7 million, respectively.

Contractual Allowances

Product Sales Discounts and Allowances

The Company records allowances for product returns, rebates and discounts at the time of sale to wholesale pharmaceutical distributors and national and regional retail chains. The Company is required to make significant judgments and estimates in determining some of these allowances. If actual results differ from its estimates, the Company will be required to make adjustments to these allowances in the future.

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Product Launch Discounts
The Company has offered additional discounts to wholesale distributors for product purchased at the time of product launch. The Company has recorded these discounts as an allowance against accounts receivable and a reduction of revenue when orders were placed.

Customer Rebates
The Company participates in certain commercial rebate programs. Under these rebate programs, the Company pays a rebate to the commercial entity or third-party administrator of the program. The Company accrues estimated rebates based on contract prices, estimated percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel and records the rebate as a reduction of revenue.

Distribution Service Fees
The Company includes distribution service fees paid to its wholesalers for distribution and inventory management services as a reduction to revenue. The Company accrues estimated fees based on contractually determined amounts, typically as a percentage of revenue, as a reduction of revenue.

Co-Pay Assistance
The Company offers discount card and other programs such as our PME program to patients under which the patient receives a discount on his or her prescription. In certain circumstances when a patient’s prescription is rejected by a managed care vendor, the Company will pay for the full cost of the prescription. The Company reimburses pharmacies for this discount through third-party vendors. The Company accrues estimated costs for co-pay assistance based on contract prices, estimated percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel and records the rebate as a reduction of revenue. The Company records the total amount of estimated costs for co-pay assistance for sales recorded in the period as a reduction of revenue.

Sales Returns
Consistent with industry practice, the Company maintains a return policy that allows customers to return product within a specified period prior to and subsequent to the product expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date and up to one year after its expiration date. The right of return expires on the earlier of one year after the product expiration date or the time that the product is dispensed to the patient. The majority of product returns result from product dating, which falls within the range set by the Company’s policy, and are settled through the issuance of a credit to the customer. The estimate of the provision for returns is based upon the Company’s historical experience with actual returns, which is applied to the level of sales for the period that corresponds to the period during which the customer may return product. This period is known to the Company based on the shelf life of products at the time of shipment. The Company records sales returns as an allowance against accounts receivable and a reduction of revenue.

Prompt Pay Discounts
As an incentive for prompt payment, the Company offers a 2% cash discount to customers. The Company expects that all customers will comply with the contractual terms to earn the discount. The Company records the discount as an allowance against accounts receivable and a reduction of revenue.
Government Rebates and Chargebacks

Government Rebates

The Company participates in certain federal government rebate programs, such as Medicare and Medicaid. The Company accrues estimated rebates based on percentages of product sold to qualified patients, estimated rebate percentages and estimated levels of inventory in the distribution channel that will be sold to qualified patients and records the rebates as a reduction of revenue.

Government Chargebacks

The Company provides discounts to federal government qualified entities with whom the Company has contracted. These federal entities purchase products from the wholesale pharmaceutical distributors at a discounted price, and the wholesale pharmaceutical distributors then charge back to the Company the difference between the current retail price and the contracted price that the federal entities paid for the products. The Company accrues estimated chargebacks based on contract prices and sell-through sales data obtained from third party information and records the chargeback as a reduction of revenue.

Bad Debt Expense

The Company’s products are sold to wholesale pharmaceutical distributors and retail chains. The Company monitors its accounts receivable balances to determine the impact, if any, of such factors as changes in customer concentration, credit risk and the realizability of its accounts receivable, and records a bad debt reserve when applicable. The Company had established an immaterial reserve for bad debt expense for the year ended December 31, 2014. For the years ended December 31, 2013 and 2012, the Company did not record a bad debt expense related to its accounts receivable balances.

Cost of Goods Sold

The Company recognizes cost of goods sold in connection with its sale of ACTIMMUNE, DUEXIS, RAYOS/LODOTRA and VIMOVO.

Cost of goods sold for ACTIMMUNE includes all costs directly related to the acquisition of ACTIMMUNE from the Company’s third party manufacturer, including freight charges and other direct expenses such as insurance and amortization of intellectual property, royalty accretion expense and any changes in estimate associated with the contingent royalty liability as described in the accrued contingent royalty accounting policy below.

Cost of goods sold for DUEXIS includes all costs directly related to the purchase of product from the Company’s third party manufacturers, including freight charges and costs of distribution service fees.

Cost of goods sold for LODOTRA includes raw material costs, costs associated with third parties who manufacture LODOTRA for the Company, supply chain costs, manufacturing overhead costs, amortization of developed technology, royalty payments to third parties for the use of certain licensed patents and applicable taxes.

Cost of goods sold for RAYOS includes all costs directly related to the purchase of product from the Company’s third party manufacturers, including freight charges, amortization of developed technology and royalty payments to third parties for the use of certain licensed patents and applicable taxes.

Cost of goods sold for VIMOVO includes all costs directly related to the acquisition of product from AstraZeneca and/or a third-party manufacturer, amortization of intellectual property, royalty accretion expense and any changes in estimate associated with the contingent royalty liability as described in the accrued contingent royalty accounting policy below.
Until the Company began recognizing revenue at the point of sale of DUEXIS to the wholesalers in the fourth quarter of 2012, it also deferred the related DUEXIS cost of goods sold and recorded such amounts as other current assets until revenue was recognized.

**Inventories**

Inventories are stated at the lower of cost or market value, using the first-in, first-out convention. Inventories consist of raw materials, work-in-process and finished goods. The Company has entered into manufacturing and supply agreements for the manufacture or purchase of raw materials and production supplies. The Company’s inventories include the direct purchase cost of materials and supplies and manufacturing overhead costs. As of December 31, 2014 and 2013, the Company had inventories of $16.9 million and $8.7 million, respectively.

Inventories exclude product sample inventory, which is included in other current assets and is expensed as a component of sales and marketing expense when provided to physicians or healthcare providers. As of December 31, 2014 and 2013, the Company had product sample inventory of $4.0 million and $1.3 million, respectively.

**Preclinical Studies and Clinical Trial Accruals**

The Company’s preclinical studies and clinical trials have historically been conducted by third-party contract research organizations and other vendors. Preclinical study and clinical trial expenses are based on the services received from these contract research organizations and vendors. Payments depend on factors such as the milestones accomplished, successful enrollment of certain numbers of patients and site initiation. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company adjusts the accrual accordingly. To date, the Company has had no significant adjustments to accrued clinical expenses.

**Net Loss Per Share**

Basic net loss per share is computed by dividing net loss by the weighted-average number of ordinary shares outstanding during the period. For the periods presented, the Company’s potential dilutive shares, which include shares issuable upon the exercise of outstanding stock options, unvested restricted stock units, warrants to purchase ordinary shares and ordinary shares associated with the potential conversion of the Company’s 5.00% Convertible Senior Notes due 2018 (“Convertible Senior Notes”) have not been included in the computation of diluted net loss per share for the periods presented in which there is a net loss as the result would be anti-dilutive. Such potentially dilutive shares are excluded when the effect would be to reduce net loss per share.

**Cash and Cash Equivalents**

Cash and cash equivalents primarily consist of cash balances and money market funds. Cash and cash equivalents were $218.8 million and $80.5 million as of December 31, 2014 and 2013, respectively. The Company’s policy is to invest excess cash in money market funds, which are generally of a short-term duration based upon operating requirements.

**Restricted Cash**

Restricted cash consists of balances included in interest-bearing money market accounts required by a vendor for the Company’s sponsored employee credit card program and by the lessor for the Company’s office in Deerfield, Illinois. As of each of December 31, 2014 and 2013, the Company had restricted cash of $0.7 million.
The carrying amounts of the Company’s financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses, approximate their fair values due to their short maturities.

At December 31, 2013 and at the final measurement date of June 27, 2014, the estimated fair value of the Company’s derivative liability related to the convertible portion of the Convertible Senior Notes was derived utilizing the binomial lattice approach for the valuation of convertible instruments. Assumptions used in the calculation included, among others, determining the appropriate credit spread using benchmarking analysis and solving for the implied credit spread, calculating the fair value of the stock component using a discounted risk free rate and borrowing cost and calculating the fair value of the note component using a discounted credit adjusted discount rate. Based on the assumptions used to determine the fair value of the derivative liability associated with the Convertible Senior Notes, the Company concluded that these inputs were Level 3 inputs.

The Company accounts for business combinations in accordance with the pronouncement guidance in ASC 805, Business Combinations, in which acquired assets and liabilities are measured at their respective estimated fair values as of the acquisition date. The Company may be required, as in the case of intangible assets, contingent royalties or derivatives, to determine the fair value associated with these amounts by estimating the fair value using an income approach under the discounted cash flow method, which may include revenue projections and other assumptions made by the Company to determine the fair value.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation. Depreciation is recognized using the straight-line method over the estimated useful lives of the related assets for financial reporting purposes and an accelerated method for income tax reporting purposes. Upon retirement or sale of an asset, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in operations. Repair and maintenance costs are charged to expenses as incurred and improvements are capitalized.

Leasehold improvements are amortized on a straight-line basis over the term of the applicable lease, or the useful life of the assets, whichever is shorter.

Depreciation and amortization periods for the Company’s property and equipment are as follows:

<table>
<thead>
<tr>
<th>Property</th>
<th>Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machinery and equipment</td>
<td>5-7 years</td>
</tr>
<tr>
<td>Furniture and fixtures</td>
<td>3-5 years</td>
</tr>
<tr>
<td>Computer equipment</td>
<td>3 years</td>
</tr>
<tr>
<td>Software</td>
<td>3 years</td>
</tr>
<tr>
<td>Trade show equipment</td>
<td>3 years</td>
</tr>
</tbody>
</table>

Software includes internal-use software acquired and modified to meet the Company’s internal requirements. Amortization commences when the software is ready for its intended use.

Intangible Assets

Definite-lived intangible assets are amortized over their estimated useful lives. The Company reviews its intangible assets when events or circumstances may indicate that the carrying value of these assets exceeds their fair value. The Company measures fair value based on the estimated future discounted cash flows associated with
These assets in addition to other assumptions and projections that the Company deems to be reasonable and supportable. The estimated useful lives for all identified intangible assets that are subject to amortization are as follows:

<table>
<thead>
<tr>
<th>Intangible Asset</th>
<th>Estimated Useful Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTIMMUNE developed technology</td>
<td>13 years</td>
</tr>
<tr>
<td>LODOTRA and RAYOS developed technology</td>
<td>12 years</td>
</tr>
<tr>
<td>PENNSAID 2% developed technology</td>
<td>6 years</td>
</tr>
<tr>
<td>VIMOVO intellectual property</td>
<td>5 years</td>
</tr>
<tr>
<td>Customer relationships</td>
<td>10 years</td>
</tr>
</tbody>
</table>

Indefinite-lived intangible assets consist of capitalized in-process research and development ("IPR&D"). IPR&D assets represent capitalized incomplete research projects that the Company acquired through business combinations. Such assets are initially measured at their acquisition date fair values and are tested for impairment, until completion or abandonment of R&D efforts associated with the projects. An IPR&D asset is considered abandoned when R&D efforts associated with the asset have ceased, and there are no plans to sell or license the asset or derive value from the asset. At that point, the asset is considered to be disposed of and is written off. Upon successful completion of each project, the Company will make a determination about the then-reaining useful life of the intangible asset and begin amortization. The Company tests its indefinite-lived intangibles, including IPR&D assets, for impairment annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired.

Research and Development Expenses

Research and development expenses include, but are not limited to, payroll and other personnel expenses, consultant expenses, expenses incurred under agreements with contract research organizations to conduct clinical trials and expenses incurred to manufacture clinical trial materials.

Sales and Marketing Expenses

Sales and marketing expenses consist principally of payroll of sales representatives and marketing and support staff, travel and other personnel-related expenses, marketing materials and distributed sample inventories. In addition, sales and marketing expenses include the Company’s medical affairs expenses, which consist of expenses related to scientific publications, health outcomes, biostatistics, medical education and information, and medical communications.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that may potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents. The Company’s cash and cash equivalents are invested in deposits with various banks in the United States, Ireland, Bermuda, Switzerland and Germany that management believes are creditworthy. At times, deposits in these banks may exceed the amount of insurance provided on such deposits. To date, the Company has not experienced any losses on its deposits of cash and cash equivalents.

The purchase cost of ACTIMMUNE under a contract with Boehringer Ingelheim as well as sales contracts relating to LODOTRA are principally denominated in Euros and are subject to significant foreign currency risk. The Company also incurs certain operating expenses in currencies other than the U.S. dollar in relation to its Ireland operations and other foreign subsidiaries, including Horizon Pharma AG; therefore, the Company is subject to volatility in cash flows due to fluctuations in foreign currency exchange rates, particularly changes in the Euro. To date, the Company has not entered into any hedging contracts since exchange rate fluctuations have had minimal impact on its results of operations and cash flows.
To achieve profitable operations, the Company must successfully develop, obtain regulatory approval for, manufacture and market its products and product candidates, and/or acquire or in-license products from third parties. There can be no assurance that any additional products can be developed, will be approved for marketing by the regulatory authorities, or can be manufactured at an acceptable cost and with appropriate performance characteristics or that any new or existing products can be successfully marketed, acquired or in-licensed by the Company. These factors could have a material adverse effect on the Company’s operations.

The Company relies on third parties to manufacture its commercial supplies of ACTIMMUNE, DUEXIS, PENNSAID 2%, RAYOS/LODOTRA, and VIMOVO. The commercialization of any of its products or product candidates could be stopped, delayed or made less profitable if those third parties fail to provide the Company with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

The Company is required to maintain compliance with applicable Swiss laws with respect to its Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. The Company reviews on a regular basis whether its Swiss subsidiary is overindebted. As of December 31, 2014, Horizon Pharma AG was not overindebted. However, Horizon Pharma AG has previously been overindebted, including at December 31, 2013, primarily as a result of operating losses at the subsidiary. The Company will continue to monitor and review Horizon Pharma AG’s financial position and, as necessary, will address any overindebtedness until such time as Horizon Pharma AG generates positive income at a statutory level, which could require the Company to have cash at Horizon Pharma AG in excess of its near-term operating needs and could affect the Company’s ability to have sufficient cash at its other operating subsidiaries to meet its near-term operating needs. As of December 31, 2014 and 2013, Horizon Pharma AG had cash and cash equivalents of $3.0 million and $3.5 million, respectively. Based upon the cash and cash equivalents held by Horizon Pharma AG as of December 31, 2014 and 2013, the Company does not expect that its financial position or results of operations will be materially affected by any need to address overindebtedness at Horizon Pharma AG. To date, the overindebtedness of Horizon Pharma AG has not resulted in the need to divert material cash resources from the Company’s other operating subsidiaries.

Historically, the Company’s accounts receivable balances have been highly concentrated with a select number of customers, consisting primarily of large wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. For the year ended December 31, 2014, the Company’s top five customers, American Specialty Pharmacy, Inc., AmerisourceBergen, Cardinal Health, Inc., McKesson Corporation and Rochester Drug Company accounted for approximately 86% of total consolidated gross sales. For the year ended December 31, 2013, the Company’s top five customers, AmerisourceBergen, Cardinal Health, Inc., McKesson Corporation, Mundipharma and Rochester Drug Company, accounted for approximately 89% of total consolidated gross sales.


Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss) (“OCI”). OCI includes certain changes in shareholders’ equity that are excluded from net income (loss), which consist of foreign currency translation adjustments. In February 2013, the Company adopted a prospective basis Financial Accounting Standards Board (“FASB”) Accounting Standards Update 2013-02, Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income (“ASU 2013-02”). ASU 2013-02 requires an entity to report the effect of significant reclassifications out of accumulated OCI on the respective
line items in net income if the amount being reclassified is required under GAAP to be reclassified in its entirety to net income. For other amounts that are not required under GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under GAAP that provide additional detail about those amounts. As of December 31, 2014 and 2013, accumulated other comprehensive loss was $4.4 million and $2.4 million, respectively.

Stock-Based Compensation

The Company accounts for stock-based compensation using the fair value method. The fair value of awards granted is estimated at the date of grant and recognized as expense on a straight-line basis over the requisite service period with the offsetting credit to additional paid-in capital. For awards with service and/or performance conditions, the total amount of compensation expense to be recognized is based on the number of awards expected to vest and is adjusted to reflect those awards that do ultimately vest. For awards with performance conditions, the Company recognizes the compensation expense if and when the Company concludes that it is probable that the performance condition will be achieved. The Company reassesses the probability of achieving the performance condition at each reporting date.

The Company also accounts for stock options issued to non-employees based on the stock options’ estimated fair value. The fair value of equity awards granted to non-employees are re-measured at each reporting date, and the resulting change in the fair value associated with such awards, if any, is recognized as a corresponding increase or reduction to stock-based compensation during the period.

Accrued Contingent Royalties

The Company’s accrued contingent royalties consist of the contingent royalty obligations assumed by the Company related to the Company’s acquisitions of the U.S. rights to VIMOVO and related to ACTIMMUNE. At the time of each acquisition, the Company assigned an estimated fair value to its contingent liability for royalties. The estimated royalty liability was based on anticipated revenue streams utilizing the income approach under the discounted cash flow method. The estimated liability for royalties is increased over time to reflect the change in its present value and accretion expense is recorded as part of cost of goods sold. The Company evaluates the adequacy of the estimated contingent royalty liability at least annually, or whenever events or changes in circumstances indicate that an evaluation of the estimate is necessary. As part of any evaluation, the Company adjusts the carrying value of the liability to the present value of the revised estimated cash flows using the original discount rate. Any decrease or increase to the liability is recorded as an increase or reduction in cost of goods sold. The royalty liability is included in current and long-term accrued royalties on the consolidated balance sheets.

New Accounting Pronouncements

From time to time, the Company adopts, as of the specified effective date, new accounting pronouncements issued by the FASB or other standard setting bodies. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company’s financial position or results of operations upon adoption.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern. ASU No. 2014-15 is intended to define management’s responsibility to evaluate whether there is substantial doubt about an organization’s ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity’s ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). ASU No. 2014-15 provides guidance to an organization’s management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly
provided by organizations in the financial statement footnotes. ASU No. 2014-15 is effective for annual reporting periods ending after December 15, 2016 and to annual and interim periods thereafter. Early adoption is permitted. The Company is currently in the process of evaluating the impact of adoption of ASU No. 2014-15 to its consolidated financial statements and related disclosures.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606): Revenue from Contracts with Customers, which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The new standard will be effective for the Company on January 1, 2017 and early adoption is not permitted. The new standard permits the use of either the retrospective or cumulative effect transition method on adoption. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures, including which transition method it will adopt.

In November 2014, the FASB issued ASU No. 2014-16, Derivatives and Hedging (Topic 815): Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share is More Akin to Debt or to Equity. ASU No. 2014-16 clarifies how current guidance should be interpreted in evaluating the economic characteristics and risks of a host contract in a hybrid financial instrument that is issued in the form of a share. In addition, ASU No. 2014-16 clarifies that in evaluating the nature of a host contract, an entity should assess the substance of the relevant terms and features (that is, the relative strength of the debt-like or equity-like terms and features given the facts and circumstances) when considering how to weight those terms and features. The effects of initially adopting ASU No. 2014-16 should be applied on a modified retrospective basis to existing hybrid financial instruments issued in a form of a share as of the beginning of the fiscal year for which the amendments are effective. Retrospective application is permitted to all relevant prior periods. ASU No. 2014-16 is effective for fiscal years and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted. The Company is evaluating the impact of adoption of ASU No. 2014-16 on our consolidated financial statements and related disclosures.

NOTE 3 – EARNINGS (LOSS) PER SHARE

The following table presents basic and diluted loss per share for the years ended December 31, 2014, 2013 and 2012 as follows (in thousands, except share and per share data):

<table>
<thead>
<tr>
<th>Basic and diluted earnings per share calculation:</th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss</td>
<td>(263,603)</td>
<td>(149,005)</td>
<td>(87,794)</td>
</tr>
<tr>
<td>Weighted average of common shares outstanding</td>
<td>83,751,129</td>
<td>63,657,924</td>
<td>38,871,422</td>
</tr>
<tr>
<td>Basic and diluted net loss per share</td>
<td>(3.15)</td>
<td>(2.34)</td>
<td>(2.26)</td>
</tr>
</tbody>
</table>

The following outstanding securities in the table below were excluded from the computation of diluted loss per share for the years ended December 31, 2014, 2013 and 2012 due to being potentially anti-dilutive:

| For the Years Ended December 31, |
|---|---|---|
| Stock options | 7,027,683 | 4,411,080 | 2,746,918 |
| Restricted stock units | 1,618,502 | 934,005 | 457,158 |
| Warrants | 6,683,811 | 16,114,746 | 17,480,243 |
| Convertible Senior Notes | 11,369,398 | 13,164,951 | — |

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NOTE 4 – BUSINESS ACQUISITIONS

PENNSAID 2% acquisition

On October 17, 2014, the Company acquired the U.S. rights to PENNSAID 2% from Nuvo for $45.0 million in cash. PENNSAID 2% is approved in the United States for the treatment of the pain of OA of the knee(s). The Company began marketing PENNSAID 2% in January 2015, and as such no sales or cost of goods sold were recognized in 2014.

As part of the acquisition, the Company entered into an eight-year exclusive supply agreement with Nuvo to manufacture and supply PENNSAID 2% to the Company. The initial term of the supply agreement is through December 31, 2022, but the agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party.

Pursuant to ASC Topic 805, Business Combinations, the Company accounted for the acquisition of the U.S. rights to PENNSAID 2% under the acquisition method of accounting, in which the Company recognized and accounted for the acquisition of the U.S. rights to PENNSAID 2% as a business combination. Using this methodology, the Company allocated the entire purchase price of $45.0 million to a developed technology intangible asset.

The valuation of the developed technology intangible asset was based on management’s estimates, forecasted financial information and reasonable and supportable assumptions. The allocation was generally based on the Company’s estimated fair value of the rights to payments with respect to U.S. revenue associated with PENNSAID 2% which were acquired in the transaction. This estimated fair value was determined using the income approach under the discounted cash flow method. Significant assumptions used in valuing the developed technology intangible asset included revenue projections through 2021 based on assumptions relating to pricing and reimbursement rates, market size and market penetration rates and cost of goods sold based on current manufacturing experience, general and administrative expenses, sales and marketing expenses, and research and development expenses for clinical and regulatory support. The calculated value of the PENNSAID 2% developed technology intangible asset is amortized using the straight-line method over an estimated useful life of 6 years, which is the period in which the majority of the benefits from such developed technology will be recognized.

Vidara acquisition

On March 18, 2014, the Company, Vidara Holdings, Vidara, U.S. HoldCo and Merger Sub, entered into the Merger Agreement. The Merger Agreement provided for the merger of Merger Sub with and into HPI, with HPI continuing as the surviving corporation and as a wholly-owned, indirect subsidiary of Vidara, with Vidara converting to a public limited company and changing its name to Horizon Pharma plc.

At the effective time of the Merger on September 19, 2014 (the “Effective Time”), (i) each share of HPI’s common stock issued and outstanding was converted into one ordinary share of New Horizon; (ii) each equity plan of HPI was assumed by New Horizon and each outstanding option under HPI’s equity plans was converted into an option to acquire the number of ordinary shares of New Horizon equal to the number of common stock underlying such option immediately prior to the Effective Time at the same exercise price per share as such option of HPI, and each other stock award that was outstanding under HPI’s equity plans was converted into a right to receive, on substantially the same terms and conditions as were applicable to such equity award before the Effective Time, the number of ordinary shares of New Horizon equal to the number of shares of HPI’s common stock subject to such stock award immediately prior to the Effective Time; (iii) each warrant to acquire HPI’s common stock outstanding immediately prior to the Effective Time and not terminated as of the Effective Time, the number of ordinary shares of New Horizon equal to the number of shares of HPI’s common stock underlying such warrant immediately prior to the Effective Time; and
(iv) the Convertible Senior Notes of HPI remained outstanding and, pursuant to a supplemental indenture entered into effective as of the Effective Time, have become convertible into the same number of ordinary shares of New Horizon at the same conversion rate in effect immediately prior to the Effective Time. Vidara Holdings retained ownership of 31,350,000 ordinary shares of New Horizon at the Effective Time. Upon consummation of the Merger (the “Closing”), the security holders of HPI (excluding the holders of HPI’s Convertible Senior Notes) owned approximately 74% of New Horizon and Vidara Holdings owned approximately 26% of New Horizon. At the Closing, New Horizon made a cash payment of $210.9 million to Vidara Holdings and $2.7 million to Citibank N.A. as escrow agent under an escrow agreement associated with the Merger.

The total consideration for the acquisition of Vidara was $601.4 million representing the $387.8 million market value of the 31,350,000 New Horizon ordinary shares that were held by prior Vidara shareholders immediately following the closing of the Merger plus the cash consideration of $213.6 million. The value of the New Horizon ordinary shares of $387.8 million is based on the September 18, 2014 closing stock price of HPI common stock of $12.37, the last closing price prior to the effective time of the Merger.

Pursuant to ASC Topic 805, *Business Combinations*, the Company accounted for the Merger as a reverse acquisition, under the acquisition method of accounting, with HPI treated as the acquiring company for accounting purposes. Identifiable assets and liabilities of Vidara, including identifiable intangible assets, were recorded based on their estimated fair values as of the date of the closing of the Merger. The excess of the fair value of the net assets acquired over the value of consideration was recorded as a bargain purchase gain. The following table summarizes the preliminary fair values assigned to the assets acquired and the liabilities assumed by the Company pursuant to the Merger, along with the resulting bargain purchase gain (in thousands):

<table>
<thead>
<tr>
<th>Allocation</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>34,401</td>
</tr>
<tr>
<td>Accounts receivable, net</td>
<td>11,838</td>
</tr>
<tr>
<td>Inventories</td>
<td>15,422</td>
</tr>
<tr>
<td>Other receivable—net working capital adjustment</td>
<td>195</td>
</tr>
<tr>
<td>Prepaid expenses</td>
<td>138</td>
</tr>
<tr>
<td>Property and equipment</td>
<td>289</td>
</tr>
<tr>
<td>Deferred tax assets</td>
<td>2,907</td>
</tr>
<tr>
<td>Customer relationships</td>
<td>8,100</td>
</tr>
<tr>
<td>In-process research and development</td>
<td>66,000</td>
</tr>
<tr>
<td>Developed technology</td>
<td>560,000</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>(1,781)</td>
</tr>
<tr>
<td>Accrued expenses and other current liabilities</td>
<td>(32,372)</td>
</tr>
<tr>
<td>Contingent royalties</td>
<td>(33,600)</td>
</tr>
<tr>
<td>Other liabilities</td>
<td>(775)</td>
</tr>
<tr>
<td>Deferred tax liabilities</td>
<td>(7,170)</td>
</tr>
<tr>
<td>Bargain purchase gain</td>
<td>(22,171)</td>
</tr>
<tr>
<td>Fair value of consideration paid</td>
<td>601,421</td>
</tr>
</tbody>
</table>

The fair value of the developed technology, IPR&D, customer relationships and contingent royalties, along with any associated deferred tax assets or liabilities, are pending final valuations being performed with assistance by an independent appraisal firm.

Inventories acquired included raw materials and finished goods. Fair value of finished goods has been determined based on the estimated selling price, net of selling costs and a margin on the selling costs. Fair value of raw materials has been estimated to equal the replacement cost. A step up in the value of inventory of $142.2 million was recorded in connection with the Merger. As of December 31, 2014, the remaining balance of ACTIMMUNE inventory step-up was $3.2 million.

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Other tangible assets and liabilities were valued at their respective carrying amounts as management believes that these amounts approximate their current fair values.

Identifiable intangible assets and liabilities acquired included developed technology, in-process research and development and customer relationships. The fair value of intangible assets is based on management’s estimates, forecasted financial information and reasonable and supportable assumptions. Estimated useful lives are based on the time periods during which the intangibles are expected to result in incremental cash flows.

Developed technology intangible assets reflect the estimated value of Vidara’s rights to the marketed ACTIMMUNE product as of the acquisition date. The fair value of developed technology was determined using an income approach. The income approach explicitly recognizes that the fair value of an asset is premised upon the expected receipt of future economic benefits such as earnings and cash inflows based on sales projections and estimated direct costs for ACTIMMUNE. Indications of value are developed by discounting these benefits to their present value at a discount rate of 15% that reflects the return requirements of the market. The fair value of developed technology was recorded as an intangible asset as of the acquisition date and subsequently amortized over an estimated remaining life of 13 years.

IPR&D is related to one R&D project for the application of ACTIMMUNE in the treatment of FA, that was incomplete at the time of the Merger. IPR&D is considered separable from the business as the project could be sold to a third party. The fair value of IPR&D was determined using an income approach. The income approach explicitly recognizes that the fair value of an asset is premised upon the expected receipt of future economic benefits such as earnings and cash inflows based on sales projections and estimated direct costs. Indications of value are developed by discounting these benefits to their present value at a discount rate of 33% that reflects the return requirements of the market. The fair value of the IPR&D was recorded as an indefinite-lived intangible asset and will be tested for impairment until completion or abandonment of R&D efforts associated with the project. In February 2015, the Company submitted an IND application for a Phase 3 study that will evaluate ACTIMMUNE in the treatment of FA and the Company plans to begin the Phase 3 study in the second quarter of 2015 in collaboration with the Friedreich’s Ataxia Research Alliance and the investigators and clinics of Friedreich’s Ataxia Research Alliance’s Collaborative Clinical Research Network in FA.

Customer relationships intangible assets reflect the estimated value of Vidara’s customer base for ACTIMMUNE. Vidara’s customers as of the acquisition date were predominantly a small group of retail pharmacies with demand for ACTIMMUNE. As such, a significant portion of revenue growth is expected to be generated from existing customers as of the acquisition date. Management assessed the historical customer trends to identify the anticipated attrition. The fair value of customer relationships was recorded as an intangible asset as of the acquisition date and subsequently amortized over an estimated remaining life of 10 years.

The Company has assigned a fair value to a contingent liability for royalties potentially payable under previously existing royalty and licensing agreements related to ACTIMMUNE. The royalties are payable under the terms of the license agreement with Genentech Inc., which was the original developer of ACTIMMUNE and under the terms of its agreement with Connetics Corporation (which was the predecessor parent company to InterMune and is now part of GlaxoSmithKline). See footnote 14 for details of the percentages payable under both license agreements. The initial fair value of this liability of $33.6 million was determined using a discounted cash flow analysis incorporating the estimated future cash flows of royalty payments resulting from future sales. The discount rates used were the same as for the fair value of the intangible assets. The estimated liability for royalties will be increased over time to reflect the change in its present value and accretion expense will be recorded as part of cost of goods sold. The estimated liability will be periodically assessed based on events and circumstances and any change will be recorded in New Horizon’s consolidated statement of operations. During the fourth quarter of 2014, as the result of a price increase for ACTIMMUNE approved to take effect on January 1, 2015, the Company reassessed the value of the estimated royalty liability and recorded a charge of $1.3 million to cost of goods sold to increase the carrying value of the contingent royalties to reflect the updated estimates.
Deferred tax assets and liabilities arise from acquisition accounting where book values of certain assets and liabilities differ from their tax bases. Deferred tax assets and liabilities are recorded at the currently enacted rates which will be in effect at the time the temporary differences are expected to reverse in the country where the underlying assets and liabilities are located (United States or Bermuda). Customer relationships intangible assets are located in the United States where a U.S. tax rate of 39% is being utilized and a deferred tax liability is recorded. Developed technology and IPR&D assets are located in Bermuda which does not levy corporate income taxes; accordingly, no deferred tax liabilities were recorded related to these intangible assets.

The excess of the estimated fair values of net assets acquired over the acquisition consideration paid has been recorded as a bargain purchase gain in the condensed consolidated statement of comprehensive income. As previously stated, the total consideration included a fixed number of New Horizon ordinary shares. The bargain purchase gain of $22.2 million is primarily the result of the decrease in the market value of our ordinary shares from the time that the Merger Agreement was signed to the Effective Time of the Merger.

For the year ended December 31, 2014, the Company recognized $25.3 million of ACTIMMUNE net sales.

**VIMOVO acquisition**

On November 18, 2013, the Company entered into agreements with AstraZeneca and Pozen pursuant to which the Company acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs, in the United States. VIMOVO, a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a proton pump inhibitor, layer surrounding the core, was approved by the FDA in 2010 for the relief of the signs and symptoms of OA, RA and AS, and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

Pursuant to the transactions contemplated by the asset purchase agreement, the Company acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the IND and NDA for VIMOVO in the United States, AstraZeneca’s interest in certain patents covering VIMOVO in the United States and certain promotional materials and records related to VIMOVO in the United States. In consideration for the U.S. rights to VIMOVO, the Company paid to AstraZeneca a one-time upfront cash payment of $35.0 million. The Company is also entitled to the benefit of a covenant not to sue granted by Merck Sharp & Dohme Corp. and certain of its affiliates (collectively, “Merck”) to AstraZeneca, with respect to certain patents owned by AstraZeneca but exclusively licensed to Merck, that cover the manufacture and commercialization of VIMOVO in the United States. In addition, AstraZeneca assigned to the Company its amended and restated collaboration and license agreement for the United States with Pozen pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States. The terms of the amended and restated collaboration and license agreement for the United States with Pozen (the “Pozen license agreement”) are described below.

In November 2013, in connection with the closing of the transactions contemplated by the asset purchase agreement, the Company also entered into a license agreement with AstraZeneca, a supply agreement with AstraZeneca’s affiliate, AstraZeneca LP, and certain other agreements that are described below. The Company also executed a transition agreement with AstraZeneca pursuant to which AstraZeneca transitioned to the Company regulatory and commercial responsibility for VIMOVO in the United States. From the closing of the transaction until December 31, 2013, AstraZeneca continued to commercialize VIMOVO in the United States under AstraZeneca’s existing pricing and paid to the Company the net profits recognized on sales of VIMOVO in the United States. Beginning January 2, 2014, the Company commenced commercialization of VIMOVO in the United States on its own behalf and under new pricing for VIMOVO. The Company is responsible for and controls matters relating to VIMOVO in the United States, including responsibility for commercialization of
VIMOVO in the United States, responsibility for ongoing developmental and regulatory activities with respect to VIMOVO in the United States and responsibility for the current VIMOVO litigation with respect to the patents the Company purchased under the asset purchase agreement and the patents the Company licensed from Pozen under the Pozen license agreement. AstraZeneca is responsible for and retains control of VIMOVO outside the United States.

In connection with the closing of the transactions contemplated by the asset purchase agreement, the Company entered into a license agreement with AstraZeneca (the “AstraZeneca license agreement”), pursuant to which AstraZeneca granted the Company an exclusive license under certain intellectual property (including patents, know-how, trademarks, copyrights and domain names) of AstraZeneca and its affiliates to develop, manufacture and commercialize VIMOVO in the United States. AstraZeneca also granted the Company a non-exclusive license under certain intellectual property of AstraZeneca and its affiliates to manufacture, import, export and perform research and development activities with respect to VIMOVO outside the United States but solely for purposes of commercializing VIMOVO in the United States. In addition, AstraZeneca granted the Company a non-exclusive right of reference and use under certain regulatory documentation controlled by AstraZeneca and its affiliates to develop, manufacture and commercialize VIMOVO in the United States and to manufacture, import, export and perform research and development activities with respect to VIMOVO outside the United States but solely for purposes of commercializing VIMOVO in the United States.

Under the AstraZeneca license agreement, the Company granted AstraZeneca a non-exclusive sublicense under such licensed intellectual property and a non-exclusive right of reference under certain regulatory documentation controlled by the Company to manufacture, import, export and perform research and development activities with respect to VIMOVO in the United States but solely for purposes of commercializing VIMOVO outside the United States.

Under the AstraZeneca license agreement, the Company and its affiliates are subject to certain limitations and restrictions on its ability to develop, commercialize and seek regulatory approval with respect to VIMOVO or other products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs (excluding DUEXIS). These limitations and restrictions include, among other things, restrictions on indications for which the Company may commercialize VIMOVO or any such other products, restrictions on the Company’s ability to develop or seek regulatory approval with respect to such other products that contain esomeprazole, restrictions on the Company’s ability to develop or seek regulatory approval for VIMOVO for any indications other than the indications for which NSAIDs are indicated, and restrictions on the Company’s marketing activities with respect to VIMOVO and any such other products.

Under the Pozen license agreement, Pozen granted to the Company an exclusive, royalty-bearing license under certain of Pozen’s intellectual property in the United States to manufacture, develop and commercialize VIMOVO and other products controlled by the Company that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs (excluding DUEXIS) in the United States.

Under the Pozen license agreement, the Company is required to pay Pozen a flat 10% royalty on net sales of VIMOVO and such other products sold by the Company, its affiliates or sublicensees during the royalty term, subject to minimum annual royalty obligations of $5.0 million in 2014 and $7.5 million each year thereafter, which minimum royalty obligations will continue for each year during which one of Pozen’s patents covers such products in the United States and there are no competing products in the United States. The royalty rate may be reduced to a mid-single digit royalty rate as a result of loss of market share to competing products. The Company’s obligation to pay royalties to Pozen will expire upon the later of (a) expiration of the last-to-expire of certain patents covering such products in the United States, and (b) ten years after the first commercial sale of such products in the United States. In addition, the Company is obligated to reimburse Pozen for costs, including attorneys’ fees, incurred by Pozen in connection with VIMOVO patent litigation moving forward, subject to agreed caps.
Under the Pozen license agreement, the Company is responsible for and is required to use diligent and reasonable efforts to commercialize VIMOVO or another qualified product in the United States. The Company also owns and maintains all regulatory filings and marketing approvals in the United States for any such products, including all INDs and NDAs for VIMOVO. Pozen has covenanted that it will not at any time prior to the expiration of the royalty term, and will ensure that its affiliates do not, directly or indirectly, develop or commercialize or license any third party to develop or commercialize certain competing products in the United States.

The Pozen license agreement, unless earlier terminated, will expire upon expiration of the royalty term for all such products in the United States. Either party has the right to terminate the agreement upon any uncured material breach by the other party or upon the bankruptcy or similar proceeding of the other party. The Company also has the right to terminate the Pozen license agreement for cause upon certain defined product failures.

In November 2013, in connection with the asset purchase agreement, the Company, AstraZeneca and Pozen entered into a letter agreement in which Pozen consented to AstraZeneca’s assignment of the Pozen license agreement to the Company and that addresses the rights and responsibilities of the parties in relation to the Pozen license agreement and the amended and restated collaboration and license agreement between Pozen and AstraZeneca for territories outside the United States (the “Pozen-AstraZeneca license agreement”). Under the letter agreement, the Company and AstraZeneca agreed to pay Pozen milestone payments upon the achievement by the Company and AstraZeneca, collectively, of certain annual aggregate global sales thresholds ranging from $550.0 million to $1.25 billion with respect to products licensed by Pozen to the Company under the Pozen license agreement and to AstraZeneca under the Pozen-AstraZeneca license agreement. The aggregate milestone payment amount that may be owed by AstraZeneca and the Company, collectively, under the letter agreement is $260.0 million, with the amount payable by each of the Company and AstraZeneca with respect to each milestone to be based upon the proportional sales achieved by each of the Company and AstraZeneca, respectively, in the applicable year.

The letter agreement will terminate with respect to Pozen and the Company upon the termination of the Pozen license agreement and will terminate with respect to Pozen and AstraZeneca upon the termination of the Pozen-AstraZeneca license agreement.

In November 2013, in connection with the asset purchase agreement, the Company entered into a supply agreement with AstraZeneca pursuant to which AstraZeneca agreed to supply VIMOVO to the Company for commercialization in the United States through December 31, 2014. Under the supply agreement, AstraZeneca supplied the quantity of VIMOVO that the Company ordered, both for the Company’s own use and for use by the Company’s sublicensees, on a transitional basis through December 31, 2014. The Company agreed to pay a set price agreed to by the Company and AstraZeneca for quantities of VIMOVO supplied by AstraZeneca under the supply agreement.

The Company accounted for the acquisition of the U.S. rights to VIMOVO under the acquisition method of accounting, in which the Company recognized and accounted for the acquisition of the U.S. rights to VIMOVO as a business combination. Net tangible and intangible assets acquired and royalty liabilities assumed were recorded based upon their respective estimated fair values as of the acquisition date. The following table shows the fair values assigned to the assets acquired and liabilities assumed by the Company as part of the asset purchase agreement (in thousands):

<table>
<thead>
<tr>
<th>Allocation</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samples inventory</td>
<td>$ 287</td>
</tr>
<tr>
<td>VIMOVO intellectual property</td>
<td>67,705</td>
</tr>
<tr>
<td>Royalty liabilities</td>
<td>(32,992)</td>
</tr>
<tr>
<td>Total cash consideration paid</td>
<td>$ 35,000</td>
</tr>
</tbody>
</table>
The valuation of the intellectual property acquired, an identifiable intangible asset, was based on management’s estimates, forecasted financial information and reasonable and supportable assumptions. The allocation was generally based on the Company’s estimated fair value of the rights to payments with respect to U.S. revenue associated with VIMOVO which were acquired in the transaction. This estimated fair value was determined using the income approach under the discounted cash flow method. Significant assumptions used in valuing the intellectual property intangible asset included revenue projections through 2030 based on assumptions relating to pricing and reimbursement rates and market size and market penetration rates, cost of goods sold based on current manufacturing experience, general and administrative expenses, sales and marketing expenses, and research and development expenses for clinical and regulatory support. The calculated value of the VIMOVO intellectual property intangible asset is amortized using the straight-line method over an estimated useful life of 61.5 months.

Additionally, the Company assigned a fair value to its liability for royalties. The royalty liability was based on anticipated revenue streams utilizing the income approach under the discounted cash flow method. As a result, the Company recorded $33.0 million of fair value royalty payments due to Pozen, of which $24.5 million was guaranteed during the years 2014 through 2018 and $8.5 million was contingent on meeting certain revenue targets. The estimated liability for royalties is increased over time to reflect the change in its present value and accretion expense is recorded as part of cost of goods sold. During the second quarter of 2014, based on higher sales of VIMOVO during the six months June 30, 2014 versus the Company’s original expectations and the Company’s adjusted expectations for future VIMOVO sales, the Company recorded a charge of $13.0 million to cost of goods sold to increase the carrying value of the contingent royalties to reflect the updated estimates. During the fourth quarter of 2014, after the Company’s most recent five year plan was approved, the Company performed its annual assessment of the carrying value of the contingent royalty liability. The Company recorded a $3.6 million credit to cost of goods sold to decrease the amount of the contingent royalty liability to reflect the updated estimates. The effect of the reassessments during the second quarter and the fourth quarter of 2014 of the fair value of the contingent royalty liability represented a net charge of $9.4 million during the year ended December 31, 2014 to cost of goods sold to increase the amount of the contingent royalty liability.

**Pro Forma Information**

The following table represents the consolidated financial information for the Company on a pro forma basis, assuming that both the Merger and the acquisition of the U.S. rights to VIMOVO occurred as of January 1, 2013. The historical financial information has been adjusted to give effect to pro forma items that are directly attributable to the Merger and are expected to have a continuing impact on the consolidated results. These items include, among others, adjustments to record the amortization of definite-lived intangible assets, interest expense, debt discount and deferred financing costs associated with the debt in connection with the acquisitions. Additionally, the following table sets forth unaudited financial information and has been compiled from historical financial statements and other information, but is not necessarily indicative of the results that actually would have been achieved had the transactions occurred on the dates indicated or that may be achieved in the future (in thousands, except per share data):

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>As reported</td>
<td>Pro-forma adjustments</td>
</tr>
<tr>
<td></td>
<td>(Unaudited)</td>
<td>(Unaudited)</td>
</tr>
<tr>
<td>Net sales</td>
<td>$ 296,955</td>
<td>$ 50,565</td>
</tr>
<tr>
<td>Net loss</td>
<td>(263,603)</td>
<td>(5,104)</td>
</tr>
<tr>
<td>Loss per ordinary share: Basic and diluted</td>
<td>$ (3.15)</td>
<td>$ (0.06)</td>
</tr>
</tbody>
</table>
The pro forma information excludes the PENNSAID 2% acquisition as it was impracticable to include because it would require significant estimates of third-party sale amounts and would be impossible to distinguish objectively the information in those estimates. In addition, prior to the Company’s acquisition, PENNSAID 2% did not have a significant amount of sales because it was not on the market until 2014.

NOTE 5 – INVENTORIES

Inventories are stated at the lower of cost or market value. Inventories consist of raw materials, work-in-process and finished goods. The Company has entered into manufacturing and supply agreements for the manufacture or purchase of raw materials and production supplies. The Company’s inventories include the direct purchase cost of materials and supplies and manufacturing overhead costs.

In connection with the Merger, the ACTIMMUNE inventory was stepped up in value to $14.2 million as of the Merger date. As of December 31, 2014, the remaining balance of ACTIMMUNE inventory step-up was $3.2 million.

The components of inventories as of December 31, 2014 and 2013 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw materials</td>
<td>$1,184</td>
<td>$ 91</td>
</tr>
<tr>
<td>Work-in-process</td>
<td>389</td>
<td>522</td>
</tr>
<tr>
<td>Finished goods</td>
<td>15,292</td>
<td>8,088</td>
</tr>
<tr>
<td>Inventories, net</td>
<td>$16,865</td>
<td>$8,701</td>
</tr>
</tbody>
</table>

NOTE 6 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets as of December 31, 2014 and 2013 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepaid co-pay expenses</td>
<td>$6,718</td>
<td>$ 621</td>
</tr>
<tr>
<td>Product samples inventory</td>
<td>4,014</td>
<td>1,323</td>
</tr>
<tr>
<td>Prepaid software license fees</td>
<td>1,128</td>
<td>855</td>
</tr>
<tr>
<td>Prepaid FDA product and manufacturing fees</td>
<td>1,055</td>
<td>312</td>
</tr>
<tr>
<td>Prepaid insurance</td>
<td>345</td>
<td>379</td>
</tr>
<tr>
<td>Prepaid marketing expenses</td>
<td>59</td>
<td>381</td>
</tr>
<tr>
<td>Prepaid clinical trial studies</td>
<td>56</td>
<td>688</td>
</tr>
<tr>
<td>Other prepaid expenses</td>
<td>995</td>
<td>329</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>$14,370</td>
<td>$ 4,888</td>
</tr>
</tbody>
</table>
NOTE 7 – PROPERTY AND EQUIPMENT

Property and equipment as of December 31, 2014 and 2013 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th>As of December 31,</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machinery and equipment</td>
<td>$3,288</td>
<td>$2,367</td>
</tr>
<tr>
<td>Furniture and fixtures</td>
<td>576</td>
<td>113</td>
</tr>
<tr>
<td>Computer equipment</td>
<td>2,040</td>
<td>2,160</td>
</tr>
<tr>
<td>Software</td>
<td>1,481</td>
<td>775</td>
</tr>
<tr>
<td>Trade show equipment</td>
<td>392</td>
<td>228</td>
</tr>
<tr>
<td>Leasehold improvements</td>
<td>3,412</td>
<td>783</td>
</tr>
<tr>
<td>Less-accumulated depreciation</td>
<td>(3,948)</td>
<td>(2,646)</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>$7,241</td>
<td>$3,780</td>
</tr>
</tbody>
</table>

Depreciation expense for the years ended December 31, 2014, 2013 and 2012 was $1.7 million, $1.2 million and $0.8 million, respectively.

NOTE 8 – INTANGIBLE ASSETS

The Company’s intangible assets consist of developed technology related to the Company’s approved products, ACTIMMUNE, PENNSAID 2% and RAYOS in the United States, LODOTRA in Europe and VIMOVO intellectual property rights in the United States.

On November 18, 2013, in connection with the Company’s acquisition of the U.S. rights to VIMOVO, the Company capitalized $67.7 million for the U.S. intellectual property rights of VIMOVO.

On September 19, 2014, in connection with the Merger, the Company capitalized $560.0 million of developed technology, $66.0 million of IPR&D and $8.1 million of customer relationships related to ACTIMMUNE.

On October 17, 2014, in connection with the Company’s acquisition of the U.S. rights to PENNSAID 2%, the Company capitalized $45.0 million for the U.S. developed technology rights of PENNSAID 2%.

The Company tests its intangible assets for impairment when events or circumstances may indicate that the carrying value of these assets exceeds their fair value. The Company does not believe there have been any circumstances or events that would indicate that the carrying value of any of its intangible assets has been impaired at December 31, 2014 or 2013.

As of December 31, 2014 and 2013, amortizable intangible assets consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2014</th>
<th></th>
<th></th>
<th>December 31, 2013</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cost Basis</td>
<td>Accumulated Amortization</td>
<td>Currency Translation</td>
<td>Net Book Value</td>
<td>Cost Basis</td>
<td>Accumulated Amortization</td>
</tr>
<tr>
<td>Developed technology</td>
<td>$757,484</td>
<td>(51,331)</td>
<td>(9,190)</td>
<td>$696,963</td>
<td>$152,484</td>
<td>(19,254)</td>
</tr>
<tr>
<td>Customer relationships</td>
<td>8,190</td>
<td>(230)</td>
<td>—</td>
<td>7,960</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total amortizable intangible assets</td>
<td>$765,584</td>
<td>(51,561)</td>
<td>(9,190)</td>
<td>$704,333</td>
<td>$152,484</td>
<td>(19,254)</td>
</tr>
</tbody>
</table>
Amortization expense for the years ended December 31, 2014, 2013 and 2012 was $32.3 million, $8.1 million and $4.7 million, respectively. IPR&D is not amortized until successful completion of the project. As of December 31, 2014, estimated future amortization expense was as follows (in thousands):

<table>
<thead>
<tr>
<th>Year</th>
<th>Amount (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>71,298</td>
</tr>
<tr>
<td>2016</td>
<td>71,298</td>
</tr>
<tr>
<td>2017</td>
<td>71,298</td>
</tr>
<tr>
<td>2018</td>
<td>71,298</td>
</tr>
<tr>
<td>2019 and thereafter</td>
<td>419,641</td>
</tr>
<tr>
<td>Total</td>
<td>704,833</td>
</tr>
</tbody>
</table>

**NOTE 9 – OTHER ASSETS**

Other assets as of December 31, 2014 and 2013, consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>As of December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2014</td>
</tr>
<tr>
<td>Deferred financing costs</td>
<td>$11,491</td>
</tr>
<tr>
<td>Other</td>
<td>73</td>
</tr>
<tr>
<td>Other assets</td>
<td>$11,564</td>
</tr>
</tbody>
</table>

**NOTE 10 – ACCRUED TRADE DISCOUNTS AND REBATES**

Accrued trade discounts and rebates as of December 31, 2014 and 2013, consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2014</td>
</tr>
<tr>
<td>Contractual allowances</td>
<td>$55,678</td>
</tr>
<tr>
<td>Government rebates and chargebacks</td>
<td>20,437</td>
</tr>
<tr>
<td>Accrued trade discounts and rebates</td>
<td>$76,115</td>
</tr>
</tbody>
</table>

**NOTE 11 – ACCRUED EXPENSES**

Accrued expenses as of December 31, 2014 and 2013, consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>As of December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2014</td>
</tr>
<tr>
<td>Payroll related expenses</td>
<td>$20,933</td>
</tr>
<tr>
<td>Accrued excise tax</td>
<td>11,243</td>
</tr>
<tr>
<td>Professional services</td>
<td>3,825</td>
</tr>
<tr>
<td>Sales and marketing expenses</td>
<td>2,343</td>
</tr>
<tr>
<td>Accrued income taxes</td>
<td>1,400</td>
</tr>
<tr>
<td>Accrued interest</td>
<td>1,260</td>
</tr>
<tr>
<td>Deferred rent</td>
<td>1,026</td>
</tr>
<tr>
<td>Contract manufacturing expenses</td>
<td>758</td>
</tr>
<tr>
<td>Clinical and regulatory expenses</td>
<td>632</td>
</tr>
<tr>
<td>Consulting services</td>
<td>596</td>
</tr>
<tr>
<td>Accrued other</td>
<td>2,609</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>$46,625</td>
</tr>
</tbody>
</table>
In connection with the Merger, any individual who is or was an executive officer or director of HPI or New Horizon and subject to the reporting requirements of Section 16(a) of the Securities Exchange Act of 1934 at any time during the period commencing six months before and ending six months after the closing of the Merger (“Covered Individual”) is subject to an excise tax (15% in 2014) under Section 4985 of the Internal Revenue Code of 1986 on the value of certain stock compensation held at any time during the same period by the covered individual. The excise tax applies to all payments (or rights to payment) granted to the Covered Individuals by HPI or New Horizon in connection with the performance of services if the value of such payment is based on (or determined by reference to) the value of stock in HPI or New Horizon (excluding certain statutory incentive stock options and holdings in tax qualified plans). This includes any outstanding (a) unexercised nonqualified stock options, whether vested or unvested, (b) restricted stock awards that remain subject to forfeiture, (c) unvested restricted stock unit awards and (d) vested but deferred shares, in each case which are held by the Covered Individuals during this twelve month period.

After careful consideration, the New Horizon board of directors concluded that the Company would provide the Covered Individuals with a payment with respect to the excise tax, so that, on a net after-tax basis, they would be in the same position as if no such excise tax had applied to them. As a result, as of December 31, 2014, the Company has estimated a liability of $11.2 million for the payments due to those who were Covered Individuals. This amount was recorded by the Company as general and administrative expense on the consolidated statements of comprehensive loss and is included in accrued expenses on the consolidated balance sheet as of December 31, 2014. These payments are expected to be made to the Covered Individuals when the excise tax becomes due and payable in 2015. Should the Company grant stock compensation in connection with the hire of any new executive officers or addition of any new board members who become Covered Individuals at any time during the six month period following the closing of the Merger, an additional excise tax reimbursement payable for such new Covered Individuals will be incurred by the Company and a corresponding liability will be recorded.

NOTE 12 – ACCRUED ROYALTIES

Changes in the liability for royalties during the year ended December 31, 2014 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance as of December 31, 2013</td>
<td>$32,992</td>
</tr>
<tr>
<td>Assumed ACTIMMUNE accrued royalty</td>
<td>3,429</td>
</tr>
<tr>
<td>Assumed ACTIMMUNE contingent royalty liabilities</td>
<td>33,600</td>
</tr>
<tr>
<td>Remeasurement of royalty liabilities</td>
<td>10,660</td>
</tr>
<tr>
<td>Royalty payments</td>
<td>(15,489)</td>
</tr>
<tr>
<td>Accretion expense</td>
<td>9,020</td>
</tr>
<tr>
<td><strong>Balance as of December 31, 2014</strong></td>
<td><strong>74,212</strong></td>
</tr>
<tr>
<td>Less: Current portion</td>
<td>25,325</td>
</tr>
<tr>
<td><strong>Accrued royalties, net of current</strong></td>
<td><strong>48,887</strong></td>
</tr>
</tbody>
</table>

During the second quarter of 2014, based on higher sales of VIMOVO during the six months ended June 30, 2014 versus the Company’s original expectations and the Company’s adjusted expectations for future VIMOVO sales, the Company recorded a charge of $13.0 million to cost of goods sold to increase the amount of the contingent royalty liability to reflect the updated estimates. During the fourth quarter of 2014, after the Company’s most recent five year plan was approved, the Company performed its annual assessment of the carrying value of the contingent royalty liability. The Company recorded a $3.6 million credit to cost of goods sold to decrease the amount of the contingent royalty liability to reflect the updated estimates. The effect of the reassessments during the second quarter and the fourth quarter of the fair value of the contingent royalty liability represented a net charge of $9.4 million for the year ended December 31, 2014 to cost of goods sold to increase the amount of the contingent royalty liability.
During the fourth quarter of 2014, as the result of a price increase for ACTIMMUNE approved to take effect on January 1, 2015, the Company reassessed the value of the estimated royalty liability and recorded a charge of $1.3 million to cost of goods sold to increase the carrying value of the contingent royalties to reflect the updated estimates.

NOTE 13 – FAIR VALUE MEASUREMENTS

The following tables set forth the Company’s financial instruments that are measured at fair value on a recurring basis within the fair value hierarchy. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The following describes three levels of inputs that may be used to measure fair value:

Level 1 - Observable inputs such as quoted prices in active markets for identical assets or liabilities.

Level 2 - Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company utilizes the market approach to measure fair value for its money market funds. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities.

Assets and liabilities measured at fair value on a recurring basis

The following table sets forth the Company’s financial assets and liabilities at fair value on a recurring basis as of December 31, 2014 and 2013 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Level 1</td>
<td>Level 2</td>
<td>Level 3</td>
<td>Total</td>
<td></td>
</tr>
<tr>
<td>Assets:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Money market funds</td>
<td>$111,581</td>
<td>$ —</td>
<td>$ —</td>
<td>$111,581</td>
<td></td>
</tr>
<tr>
<td>Total assets at fair value</td>
<td>$111,581</td>
<td>$ —</td>
<td>$ —</td>
<td>$111,581</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2013</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Level 1</td>
<td>Level 2</td>
<td>Level 3</td>
<td>Total</td>
<td></td>
</tr>
<tr>
<td>Assets:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Money market funds</td>
<td>$66,817</td>
<td>$ —</td>
<td>$ —</td>
<td>$66,817</td>
<td></td>
</tr>
<tr>
<td>Total assets at fair value</td>
<td>$66,817</td>
<td>$ —</td>
<td>$ —</td>
<td>$66,817</td>
<td></td>
</tr>
<tr>
<td>Liabilities:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Derivative liability</td>
<td>$ —</td>
<td>$ —</td>
<td>$109,410</td>
<td>$109,410</td>
<td></td>
</tr>
<tr>
<td>Total liabilities at fair value</td>
<td>$ —</td>
<td>$ —</td>
<td>$109,410</td>
<td>$109,410</td>
<td></td>
</tr>
</tbody>
</table>

In accordance with the pronouncement guidance in ASC 815 “Derivatives and Hedging”, the conversion option included within the Convertible Senior Notes was deemed to include an embedded derivative, which required the Company to bifurcate and separately account for the embedded derivative as a separate liability on F-31.
its consolidated balance sheets. The estimated fair value was derived utilizing the binomial lattice approach for the valuation of convertible instruments. Assumptions used in the calculation included, among others, determining the appropriate credit spread using benchmarking analysis and solving for the implied credit spread, calculating the fair value of the stock component using a discounted risk free rate and borrowing cost and calculating the fair value of the note component using a discounted credit adjusted discount rate. Based on the assumptions used to determine the fair value of the derivative liability associated with the Convertible Senior Notes, the Company concluded that these inputs were Level 3 inputs.

The following table presents the assumptions used by the Company to determine the fair value of the conversion option embedded in the Convertible Senior Notes as of June 27, 2014, the date the Company’s shareholders approved the issuance of shares of HPI’s common stock in excess of 13,164,951 shares upon conversion of the Convertible Senior Notes, and December 31, 2013:

| Stock price | $15.96 | $7.62 |
| Risk free rate | 1.43% | 1.69% |
| Borrowing cost | 3.80% | 5.0% and 3.5% |
| Weights | Equal weight | Equal weight |
| Credit spread (in basis points) | 900 | 930 and 1,170 |
| Volatility | 40.00% | 40.00% |
| Initial conversion price | $5.36 | $5.36 |
| Remaining time to maturity (in years) | 4.4 | 4.9 |

On June 27, 2014, the Company’s shareholders approved the issuance of the Company’s ordinary shares in excess of 13,164,951 shares upon conversion of the Convertible Senior Notes. As such, on the date of approval, the derivative liability was re-measured to a final fair value and the entire fair value of the derivative liability of $324.4 million was reclassified to additional paid-in capital. Total losses of $215.0 million from re-measurement of the derivative liability were recorded in its results of operations for the year ended December 31, 2014.

**NOTE 14 – COMMITMENTS AND CONTINGENCIES**

**Lease Obligations**

The Company occupies approximately 10,300 square feet of office space in its headquarters in Dublin, Ireland under a lease that expires on November 4, 2029. The Company also occupies approximately 50,500 square feet of office space in Deerfield, Illinois under lease agreements that expire on June 30, 2018, approximately 5,000 square feet of office space in Mannheim, Germany under a lease that expires on December 31, 2016, approximately 3,200 square feet of office space in Reinach, Switzerland under a lease that expires on May 31, 2015 and approximately 6,200 square feet of office space in Roswell, Georgia under a lease that expires on October 31, 2018.

The Company recognizes rent expense on a monthly basis over the lease term based on a straight-line method. Rent expense was $0.6 million, $0.5 million and $0.5 million for the years ended December 31, 2014, 2013 and 2012, respectively.

As of December 31, 2014, minimum future cash payments due under lease obligations were as follows (in thousands):

<table>
<thead>
<tr>
<th>Operating Lease obligations</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020 &amp; Thereafter</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$1,581</td>
<td>$1,624</td>
<td>$1,538</td>
<td>$1,104</td>
<td>$558</td>
<td>$5,484</td>
<td>$11,889</td>
</tr>
</tbody>
</table>

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In August 2007, the Company entered into a manufacturing and supply agreement with Jagotec AG (“Jagotec”). Under the agreement, Jagotec or its affiliates are required to manufacture and supply RAYOS/LODOTRA exclusively to the Company in bulk. The Company committed to a minimum purchase of RAYOS/LODOTRA tablets from Jagotec for five years from the date of first launch of RAYOS/LODOTRA in a major country, as defined in the agreement, which was in April 2009. Thereafter, the agreement automatically renews on a yearly basis until either party provides two years advance written notice of termination. In April 2014, the agreement automatically renewed, and, therefore, the earliest the agreement can expire according to this advance notice procedure is April 15, 2017 and the minimum purchase commitment is in force until April 2017. At December 31, 2014, the minimum purchase commitment based on tablet pricing in effect under the agreement was $3.3 million through April 2017.

In May 2011, the Company entered into a manufacturing and supply agreement with sanofi-aventis U.S., and amended the agreement effective as of September 25, 2013. Pursuant to the agreement, as amended, sanofi-aventis U.S. is obligated to manufacture and supply DUEXIS to the Company in final, packaged form, and the Company is obligated to purchase DUEXIS exclusively from sanofi-aventis U.S. for the commercial requirements of DUEXIS in North America, South America and certain countries and territories in Europe, including the European Union member states and Scandinavia. At December 31, 2014, the Company had a binding purchase commitment to sanofi-aventis U.S. for DUEXIS of $2.6 million, which is to be delivered through March 2015.

In July 2013, Vidara and Boehringer Ingelheim entered into an exclusive supply agreement, which the Company assumed as of the result of the Merger. Under the agreement, Boehringer Ingelheim is required to manufacture and supply interferon gamma 1-b (ACTIMMUNE) to the Company. The Company is required to purchase minimum quantities of finished drug product per annum through July 2020. As of December 31, 2014, the minimum binding purchase commitment to Boehringer Ingelheim was $21.2 million (converted using a Dollar-to-Euro rate of 1.22).

In November 2013, the Company entered into a long-term master manufacturing services and product agreement with Patheon pursuant to which Patheon will manufacture VIMOVO for the Company through December 31, 2019. The Company agreed to purchase a specified percentage of VIMOVO requirements for the United States from Patheon. The Company must pay an agreed price for final, packaged VIMOVO supplied by Patheon as set forth in the Patheon manufacturing agreement, subject to adjustments, including certain unilateral adjustments by Patheon, such as annual adjustments for inflation and adjustments to account for certain increases in the cost of components of VIMOVO other than active materials. The Company will issue 12-month forecasts of the volume of VIMOVO that the Company expects to order. The first three months of the forecast will be considered binding firm orders. At December 31, 2014, the Company had a binding purchase commitment with Patheon for VIMOVO of $3.6 million.

In October 2014, in connection with the acquisition of the U.S. rights to PENNSAID 2% from Nuvo, the Company and Nuvo entered into an exclusive supply agreement. Under the supply agreement, Nuvo will manufacture and supply PENNSAID 2% to the Company. The initial term of our supply agreement is through December 31, 2022, but the agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party. At least 90 days prior to the first day of each calendar month during the term of the supply agreement, the Company will submit a binding written purchase order to Nuvo for PENNSAID 2% in minimum batch quantities. The Company has committed to binding purchase orders to Nuvo for delivery of PENNSAID 2% on or before April 1, 2015 of $2.7 million.
Royalty Agreements

In connection with the August 2004 development and license agreement with SkyePharma AG (“SkyePharma”) and Jagotec, a wholly-owned subsidiary of SkyePharma, regarding certain proprietary technology and know-how owned by SkyePharma, Jagotec is entitled to receive a single digit percentage royalty on net sales of RAYOS/LODOTRA and on any sub-licensing income, which includes any payments not calculated based on the net sales of RAYOS/LODOTRA, such as license fees, lump sum and milestone payments. Royalty expense recognized in cost of goods sold for the years ended December 31, 2014, 2013 and 2012 was $1.7 million, $0.9 million and $0.5 million, respectively.

Under the Pozen license agreement, the Company is required to pay Pozen a flat 10% royalty on net sales of VIMOVO and such other products sold by the Company, its affiliates or sublicensees during the royalty term, subject to minimum annual royalty obligations of $5.0 million in 2014 and $7.5 million each year thereafter, which minimum royalty obligations will continue for each year during which one of Pozen’s patents covers such products in the United States and there are no competing products in the United States. The royalty rate may be reduced to a mid-single digit royalty rate as a result of loss of market share to competing products. The Company’s obligation to pay royalties to Pozen will expire upon the later of (a) expiration of the last-to-expire of certain patents covering such products in the United States, and (b) ten years after the first commercial sale of such products in the United States.

Under the license agreement with Genentech Inc. (“Genentech”), which was the original developer of ACTIMMUNE, the Company is or was obligated to pay royalties to Genentech on its net sales of ACTIMMUNE as follows:

- Through November 25, 2014, a royalty of 45% of the first $3.7 million in net sales achieved in a calendar year, and 10% on all additional net sales in that year;
- For the period from November 26, 2014 through May 5, 2018, the royalty payments will be reduced to a 20%-30% range for the first tier in net sales and in the 1%-9% range for the second tier; and
- From May 6, 2018 and for so long as the Company continues to commercially sell ACTIMMUNE, an annual royalty in the low single digits as a percentage of annual net sales.

Under the terms of the agreement with Connetics Corporation (which was the predecessor parent company to InterMune and is now part of GlaxoSmithKline) (“Connectics”), the Company is obligated to pay royalties to Connectics on the Company’s net sales of ACTIMMUNE as follows:

- 0.25% of net sales of ACTIMMUNE, rising to 0.5% once cumulative net sales of ACTIMMUNE in the United States surpass $1.0 billion; and in the event the Company develops and receive regulatory approval for ACTIMMUNE in the indication of scleroderma, the Company will be obligated to pay a royalty of 4% on all net sales of ACTIMMUNE recorded for use in that indication.

The royalty obligations for VIMOVO and ACTIMMUNE are included in accrued royalties on the Company’s consolidated balance sheets.

Excise Tax Gross Up

In connection with the Merger, the New Horizon board of directors concluded that the Company would provide the Covered Individuals with a payment with respect to the excise tax on the value of certain stock compensation, so that, on a net after-tax basis, they would be in the same position as if no such excise tax had applied to them. As of December 31, 2014, the Company has estimated a liability of $11.2 million for the payments due to those who were Covered Individuals. This amount was recorded by the Company as general and administrative expense on the consolidated statements of comprehensive loss and is included in accrued expenses on the consolidated balance sheet as of December 31, 2014. These payments are expected to be made to the Covered Individuals when the excise tax becomes due and payable in 2015. Should the Company grant stock
compensation in connection with the hire of any new executive officers or addition of any new board members who become Covered Individuals at any time during the six month period following the closing of the Merger, an additional excise tax reimbursement payable for such new Covered Individuals will be incurred by the Company and a corresponding liability will be recorded.

Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company’s management does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company’s business, financial condition, results of operations or cash flows. In addition, the Company from time to time has billing disputes with vendors in which amounts invoiced are not in accordance with the terms of their contracts.

The Company previously entered into a rebate agreement with a pharmacy benefit manager ("PBM"), pursuant to which the Company was required to pay certain rebates on certain of its products that were reimbursed by health plans contracting with the PBM with respect to their formularies. In 2014, the Company sent a notice alerting the PBM of certain material breaches by the PBM under the agreement and indicating that the agreement would automatically terminate if the material breaches were not cured within 30 days. Among other things, the breaches by the PBM involved repeated invoices that included claims for rebates which were not eligible for payment under the agreement. Following the 30-day period, during which the PBM did not take action to cure the breaches or formally respond to the notice, the Company sent another notice informing the PBM that the agreement was terminated as of the end of the 30-day period in accordance with its terms and the Company ceased paying further rebates under the agreement. On November 6, 2014, the Company received a letter from the PBM asserting that the breaches the Company alleged in its termination notice were not material breaches and therefore the agreement was not terminated and remains in effect. In addition, the PBM claimed that the Company owes $38.5 million in past price protection and utilization rebates related to VIMOVO and DUEXIS, in addition to further rebates on sales of VIMOVO and DUEXIS continuing after the date the Company believes the agreement was terminated. The substantial majority of these rebate claims relate to price protection rebates on VIMOVO which the Company believes are precluded under the agreement, particularly because VIMOVO was not covered under the agreement until after the Company had established an initial price for VIMOVO under a Horizon-owned National Drug Code. Based upon the terms of the agreement and the PBM’s actions, the Company believes that the PBM’s claims in its November 6, 2014 letter are without merit and the Company intends to vigorously defend against them. The Company currently estimates the range of potential disputes to be in the $0 to $4.7 million range and has not recorded a liability associated with any portion of the disputed amounts as the Company does not believe payment of any such amounts is probable at this time.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company’s exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with its memorandum and articles of association, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company’s request in such capacity. Additionally, the Company has entered, and intends to continue to enter, into separate indemnification agreements with its directors and executive officers. These agreements, among other things, require the Company to indemnify its directors and executive officers for certain expenses, including attorneys’ fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of the Company’s directors or
executive officers, or any of the Company’s subsidiaries or any other company or enterprise to which the person provides services at the Company’s request. There have been no claims to date and the Company has a director and officer insurance policy that enables it to recover a portion of any amounts paid for future potential claims. Certain of the Company’s officers and directors have also entered into separate indemnification agreements with HPI prior to the Merger.

NOTE 15 – LEGAL PROCEEDINGS

On July 15, 2013, the Company received a Paragraph IV Patent Certification from Watson Laboratories, Inc.—Florida, known as Actavis Laboratories FL, Inc. (“Watson”), advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised the Company as to the timing or status of the FDA’s review of its filing. On August 26, 2013, the Company, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Watson, Actavis Pharma, Inc., Andrix Corp., and Actavis, Inc. (collectively “WLF”) seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The Company and Jagotec have granted WLF a covenant not to sue with respect to US Patent Nos. 6,677,326 and 8,168,218, respectively, and accordingly these patents have been dismissed from the lawsuit. The court held a claim construction hearing on October 16, 2014, and issued its opinion and order on claim construction on November 10, 2014, adopting our proposed construction of both of the disputed claim terms. The court has scheduled expert discovery in the WLF action to be completed by June 2, 2015, and has set the pretrial conference for September 10, 2015. The trial date will be set following the pretrial conference.

On November 13, 2014, the Company received a Paragraph IV Patent Certification from Watson advising that Watson had filed an ANDA with the FDA for a generic version of PENNSAID 2%. Watson has not advised the Company as to the timing or status of the FDA’s review of its filing. On December 23, 2014, the Company filed suit in the United States District Court for the District of New Jersey against Watson seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that Watson has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Watson’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The Court has not yet set a trial date for the Watson action.

On December 2, 2014, the Company received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,741,956 from Paddock Laboratories, LLC (“Paddock”) advising that Paddock had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On January 9, 2015, the Company received from Paddock another Paragraph IV Patent Certification against newly Orange Book listed U.S. Patent No. 8,871,809. Paddock has not advised the Company as to the timing or status of the FDA’s review of its filings. On January 13, 2015 and January 14, 2015, the Company filed suits in the United States District Court for the District of New Jersey and the United States District Court for the District of Delaware, respectively, against Paddock seeking an injunction to prevent the approval of the ANDA. The lawsuits allege that Paddock has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID 2% prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Paddock’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The Courts have not yet set trial dates for the Paddock actions.
Currently, patent litigation is pending in the United States District Court for the District of New Jersey against four generic companies intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the United States District Court for the District of New Jersey and have been consolidated for discovery purposes. They are collectively known as the VIMOVO cases, and involve the following sets of defendants: (i) Dr. Reddy’s Laboratories Inc. and Dr. Reddy’s Laboratories Ltd. (collectively, Dr. Reddy’s); (ii) Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, Lupin); (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, Mylan); and (iv) Watson Laboratories, Inc.—Florida, known as Actavis Laboratories FL, Inc. and Actavis Pharma, Inc. (collectively, Actavis). Patent litigation in the United States District Court for the District of New Jersey against a fifth generic company, Anchen Pharmaceuticals Inc. (“Anchen”), was dismissed on June 9, 2014 after Anchen recertified under Paragraph III. The Company understands that Dr. Reddy’s has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy’s is now able to commercialize VIMOVO under AstraZeneca’s Nexium patent rights. The settlement agreement, however, has no effect on the Pozen VIMOVO patents, which are still the subject of patent litigations. As part of the Company’s acquisition of the U.S. rights to VIMOVO, the Company has taken over and is responsible for the patent litigations that include the Pozen patents licensed to the Company under the Pozen license agreement.

The VIMOVO cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, January 4, 2013, May 10, 2013, June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. The Company understands the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The Company understands the Dr. Reddy’s notice letters were dated March 11, 2011 and November 20, 2012; the Lupin notice letters were dated June 10, 2011 and March 12, 2014; the Mylan notice letter was dated May 16, 2013; the Actavis notice letters were dated March 29, 2013 and November 5, 2013; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order and has set a pretrial schedule but has not yet set a trial date.

On or about December 19, 2014, the Company filed a Notice of Opposition to a European patent, EP 2611457, to Roberto Testi, et al., covering compositions and methods for treating FA with interferon gamma, e.g., ACTIMMUNE. In the European Union, the grant of a patent may be opposed by one or more private parties.

On February 2, 2015, the Company received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, and 8,871,809 from Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (collectively, “Taro”) advising that Taro had filed an ANDA with the FDA for a generic version of 2%. Taro has not advised the Company as to the timing or status of the FDA’s review of its filing. The Company is still in the process of evaluating the Paragraph IV Patent Certification, and it is anticipated the Company will file suit against Taro within the statutorily prescribed 45 day time limit.
NOTE 16 – DEBT AGREEMENTS

The Company’s outstanding debt balances as of December 31, 2014 and 2013, consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>As of December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2014</td>
</tr>
<tr>
<td>Senior Secured Credit Facility</td>
<td>$300,000</td>
</tr>
<tr>
<td>Convertible Senior Notes</td>
<td>60,985</td>
</tr>
<tr>
<td>Debt discount</td>
<td>(15,482)</td>
</tr>
<tr>
<td>Total long-term debt</td>
<td>345,503</td>
</tr>
<tr>
<td>Less: current maturities</td>
<td>48,334</td>
</tr>
<tr>
<td>Long-term debt, net of current maturities</td>
<td>$297,169</td>
</tr>
</tbody>
</table>

Convertible Senior Notes

On November 18, 2013, the Company entered into note purchase agreements with investors to issue $150.0 million aggregate principal amount of Convertible Senior Notes. The note purchase agreements contain customary representations, warranties, covenants and closing conditions. The Convertible Senior Notes were issued on November 22, 2013. The Company received net proceeds of $143.6 million from the sale of the Convertible Senior Notes, after deducting fees and expenses of $6.4 million. The Convertible Senior Notes are governed by an Indenture, dated as of November 22, 2013, between HPI and U.S. Bank National Association, as trustee (the “Indenture”). The Convertible Senior Notes bear interest at a rate of 5.00% per year, payable in arrears on May 15 and November 15 of each year, which began on May 15, 2014. The Convertible Senior Notes will mature on November 15, 2018, unless earlier repurchased or converted.

The Company used a portion of the proceeds from the Convertible Senior Notes to purchase $18.7 million related to certain capped call transactions with Deutsche Bank AG, London Branch, and Société Générale (the “counterparties”). The capped call transactions were comprised of a net settled purchased call option and a net settled sold call option. The Company purchased the call option with an initial strike price of $5.364, which was equal to the initial conversion price, and sold a call option with a strike price of $6.705, which is equal to the cap price. The number of options underlying the capped calls was 150,000 or the equivalent to the number of $1,000 Convertible Senior Notes initially issued by the Company. On September 23, 2014, the counterparties exercised their rights to terminate the capped call transactions. In connection with such termination, the Company received $14.0 million comprised of both $9.4 million in cash and 384,366 ordinary shares of the Company which were valued at $4.6 million, based on the closing share price of September 22, 2014 of $11.93 per share. The Company recorded the receipt of the ordinary shares as treasury shares. In addition, in connection with the termination of the capped call transactions, one counterparty and/or their affiliates unwound various hedging transactions with respect to the Company’s ordinary shares.

The Convertible Senior Notes were sold at a price equal to 100% of the principal amount thereof and are convertible, under certain conditions, at the option of the holders at any time prior to the close of business on the business day immediately preceding August 15, 2018. Prior to August 15, 2018, the Convertible Senior Notes are convertible, at the option of the holders thereof, only under the following circumstances:

1. Conversion upon Satisfaction of Sale Price Condition: If the closing price of the Company’s ordinary shares for at least 20 trading days during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day.

2. Conversion upon Satisfaction of Trading Price Condition: The Convertible Senior Notes can be surrendered for conversion during the five business day period after any five consecutive trading day.
period in which the trading price per $1,000 principal amount of Convertible Senior Notes was less than 98% of the product of the last reported sale price of the Company’s ordinary shares and the applicable conversion rate on such date.

3. **Conversion upon Specified Distributions:** If the Company elects to:
   
i. issue to all or substantially all holders of the Company’s ordinary shares any rights, options or warrants (other than in connection with a shareholder rights plan) entitling them, for a period of not more than 45 calendar days after the declaration date for such issuance, to subscribe for or purchase the Company’s ordinary shares at a price per share that is less than the average of the last reported sale prices of the Company’s ordinary shares for the 10 consecutive trading day period ending on, and including, the trading day immediately preceding the declaration date for such issuance; or
   
   ii. distribute to all or substantially all holders of the Company’s ordinary shares its assets, securities or rights to purchase its securities, which distribution has a per share value, as reasonably determined by the Company’s board of directors or a committee thereof, exceeding 10% of the last reported sale price of the Company’s ordinary shares on the trading day preceding the date of announcement for such distribution.

4. **Conversion upon Specified Corporate Events:** If (i) a transaction or event that constitutes a fundamental change or a make-whole fundamental change occurs or (ii) the Company is party to a consolidation, merger, binding share exchange, or transfer or lease of all or substantially all of its consolidated assets pursuant to which the Company’s ordinary shares would be converted into cash, securities or other assets.

On or after August 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date for the Convertible Senior Notes, holders will be able to convert their Convertible Senior Notes at their option at the conversion rate then in effect at any time, regardless of these conditions.

Subject to certain limitations, HPI may settle conversions of the Convertible Senior Notes by paying or delivering, as the case may be, cash, the Company’s ordinary shares or a combination of cash and the Company’s ordinary shares at HPI’s election. If the Company undergoes a fundamental change prior to the maturity date of the Convertible Senior Notes, the holders may require HPI to repurchase for cash all or any portion of their Convertible Senior Notes at a price equal to 100% of the principal amount of the Convertible Senior Notes to be repurchased, plus accrued and unpaid interest.

The conversion rate for the Convertible Senior Notes was initially 186.4280 ordinary shares per $1,000 principal amount of Convertible Senior Notes (equivalent to an initial conversion price of approximately $5.36 per ordinary share). The conversion rate of the Convertible Senior Notes, and the corresponding conversion price, is subject to adjustment for certain events, but will not be adjusted for accrued and unpaid interest. On June 30, 2014, the Company reclassified the Convertible Senior Notes from long term to short term as conditions for conversion were met.

The derivative liability was subject to revaluation on a quarterly basis to reflect the market value change of the embedded conversion option. At December 31, 2013, the Company conducted a fair value assessment of the
embedded derivative. As a result of the fair value assessment, the Company recorded a $69.3 million expense in its results of operations for the year ended December 31, 2013 to properly reflect the fair value of the embedded derivative of $109.4 million as of December 31, 2013.

On June 27, 2014, the Company's shareholders approved the issuance of the Company's ordinary shares in excess of 13,164,951 shares upon conversion of the Convertible Senior Notes. As such, on the date of approval, the derivative liability was re-measured to a final fair value and the entire fair value of the derivative liability of $324.4 million was reclassified to additional paid-in capital. Total losses of $215.0 million from re-measurement of the derivative liability were recorded in its results of operations for the year ended December 31, 2014. As of December 31, 2014, the fair value of the Convertible Senior Notes was approximately $57.0 million.

In connection with the Merger, HPI and New Horizon entered into a supplemental indenture dated as of September 19, 2014 (the “First Supplemental Indenture”) with U.S. Bank National Association (the “Trustee”) to the Indenture. Pursuant to the First Supplemental Indenture, HPI remained the obligor of the Convertible Senior Notes and the Company agreed to fully and unconditionally guaranty the obligations of HPI under the Indenture (the “Guaranty”). The First Supplemental Indenture also provides that the conversion value of the Convertible Senior Notes will be calculated by reference to the Company's ordinary shares, rather than the common stock of HPI, and any shares issuable upon conversion of the Convertible Senior Notes will be settled in the Company's ordinary shares, rather than shares of the common stock of HPI. In addition, the Company assumed the disclosure obligations required by the Indenture.

In the fourth quarter of 2014, the Company entered into separate, privately-negotiated conversion agreements with certain holders of the Convertible Senior Notes. Under the conversion agreements, the holders agreed to convert an aggregate principal amount of $89.0 million of Convertible Senior Notes held by them and the Company agreed to settle such conversions by issuing 16,594,793 ordinary shares. In addition, pursuant to the conversion agreements, the Company made an aggregate cash payment of $16.7 million to the holders for additional exchange consideration and $1.7 million of accrued and unpaid interest, and recognized a non-cash charge of $11.7 million related to the extinguishment of debt as a result of the note conversions. Immediately following the conversions of the Convertible Senior Notes contemplated by the conversion agreements, $61.0 in aggregate principal amount of the Convertible Senior Notes remained outstanding.

**Senior Secured Credit Facility**

On June 17, 2014, the Company entered into the Senior Secured Credit Facility with a group of lenders and Citibank, N.A., as administrative and collateral agent. The Senior Secured Credit Facility is governed by a Credit Agreement dated June 17, 2014. The Senior Secured Credit Facility provides for (i) a committed five-year $300.0 million term loan facility (the “Term Loan Facility”) with a portion of the proceeds used to effect the Merger and to pay fees and expenses in connection therewith, and with the balance being used for general corporate purposes; (ii) an uncommitted accordion facility subject to the satisfaction of certain financial and other conditions; and (iii) one or more uncommitted refinancing loan facilities with respect to loans thereunder. The initial borrower under the Term Loan Facility is U.S. HoldCo (renamed Horizon Pharma Holdings USA, Inc.). The Credit Agreement allows for the Company and other subsidiaries of the Company to become borrowers under the accordion facility. Loans under the Senior Secured Credit Facility bear interest, at each borrower's option, at a rate equal to either the London Inter-Bank Offer Rate (“LIBOR”), plus an applicable margin of 8.0% per year (subject to a 1.0% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 7.0% per year. The Company borrowed the full $300.0 million available on the Term Loan Facility on September 19, 2014 as a LIBOR-based borrowing. The Company paid a ticking fee to the applicable lenders of $3.2 million covering the period beginning on the date that was 31 days following the effective date of the Senior Secured Credit Facility and continuing through the closing of the Merger.

The borrowers' obligations under the Credit Agreement and any swap obligations entered into with a lender thereunder are and will be guaranteed by the Company and each of the Company’s existing and subsequently
acquired or organized direct and indirect subsidiaries (other than certain immaterial subsidiaries, subsidiaries whose guarantee would result in material adverse tax consequences and subsidiaries whose guarantee is prohibited by applicable law). The borrowers’ obligations under the Credit Agreement are secured, subject to customary permitted liens and other agreed upon exceptions, by a perfected security interest in (i) all tangible and intangible assets of the borrowers and the guarantors, except for certain customary excluded assets, and (ii) all of the capital stock owned by the borrowers and guarantors thereunder (limited, in the case of the stock of certain non-U.S. subsidiaries of U.S. HoldCo, to 65% of the capital stock of such subsidiaries).

U.S. HoldCo is permitted to make voluntary prepayments of loans under the Term Loan Facility, except that (i) a specified make-whole amount would apply to any repayment or repricing prior to the second anniversary of the Closing Date, (ii) a 4% premium would apply to any repayment or repricing on or prior to the third anniversary of the Closing Date, and (iii) a 2% premium would apply to any repayment or repricing on or prior to the fourth anniversary of the Closing Date. U.S. HoldCo is required to make mandatory prepayments of loans under the Term Loan Facility (without payment of a premium) with (a) net cash proceeds from certain non-ordinary course asset sales (subject to reinvestment rights and other exceptions), (b) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions), and (c) net cash proceeds from issuances of debt (other than certain permitted debt).

The Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. Events of default under the Credit Agreement include: (i) the failure by the borrowers to timely make payments due under the Credit Agreement; (ii) material misrepresentations or misstatements in any representation or warranty by any party when made; (iii) failure by any borrower or guarantor thereunder to comply with the covenants under the Credit Agreement and other related agreements; (iv) certain defaults under a specified amount of other indebtedness of the Company or its subsidiaries; (v) insolvency or bankruptcy-related events with respect to the Company or any of its material subsidiaries; (vi) certain undischarged judgments against the Company or any of its restricted subsidiaries; (vii) certain ERISA-related events reasonably expected to have a material adverse effect on the Company and its subsidiaries taken as a whole; (viii) certain security interests or liens under the loan documents ceasing to be, or being asserted by the Company or its restricted subsidiaries not to be, in full force and effect; and (ix) any loan document or material provision thereof ceasing to be, or any proceeding being instituted asserting that such loan document or material provision is not, in full force and effect.

As of December 31, 2014, the carrying value of the Senior Secured Credit Facility approximates its fair value due to its recent issuance.

Commitment Letter

On March 18, 2014, the Company entered into the Commitment Letter with Deerfield and certain Deerfield Funds pursuant to which the Deerfield Funds had committed to provide up to $250.0 million of senior secured loans to finance the Merger. The Company paid Deerfield a commitment fee of $5.0 million upon execution of the Commitment Letter. The $5.0 million commitment fee paid to Deerfield was capitalized as a prepaid expense and was amortized to expense through June 30, 2014. The Company allowed the Commitment Letter to expire on June 30, 2014 as a result of the execution of the Senior Secured Credit Facility.

NOTE 17 – SHAREHOLDERS’ EQUITY

In connection with the Merger, each share of HPI’s common stock issued and outstanding was converted into one ordinary share of New Horizon and each warrant to acquire HPI’s common stock outstanding immediately prior to the Effective Time and not terminated as of the Effective Time was converted into a warrant to acquire, on substantially the same terms and conditions as were applicable under such warrant before the Effective Time, the number of ordinary shares of New Horizon equal to the number of shares of HPI’s common
stock underlying such warrant immediately prior to the Effective Time. Vidara Holdings retained ownership of 31,350,000 ordinary shares of New Horizon at the Effective Time. Upon consummation of the Merger, the security holders of HPI (excluding the holders of HPI's Convertible Senior Notes) owned approximately 74% of New Horizon and Vidara Holdings owned approximately 26% of New Horizon.

As discussed in Note 16—Debt Agreements, on September 23, 2014, the Company received 384,366 of its ordinary shares as part of the settlement of the termination of the capped call transaction associated with its Convertible Senior Notes and recorded the receipt of the ordinary shares as treasury shares.

During the year ended December 31, 2014, the Company issued an aggregate of 8,440,662 ordinary shares upon the cash exercise of warrants and the Company received proceeds of $38.5 million representing the aggregate exercise price for such warrants. In addition, warrants to purchase an aggregate of 987,201 ordinary shares of the Company were exercised in cashless exercises, resulting in the issuance of 549,458 ordinary shares. Included in these cashless exercises were 162,309 warrants that were exercised in cashless exercises in connection with the Merger, resulting in an aggregate issuance of 248 ordinary shares. As of December 31, 2014, there were outstanding warrants to purchase 6,683,811 ordinary shares of the Company.

During the year ended December 31, 2014, the Company issued an aggregate of 864,780 ordinary shares in connection with the exercise of stock options and vesting of restricted stock units and received $1.6 million in proceeds in connection with the exercise of stock options. The Company also received proceeds of $1.7 million upon the issuance of 536,543 ordinary shares of the Company through its employee stock purchase program during the year ended December 31, 2014.

NOTE 18 – EQUITY INCENTIVE PLANS

Employee Stock Purchase Plan

In July 2010, HPI’s board of directors adopted the 2011 Employee Stock Purchase Plan (the “2011 ESPP”). In June 2011, HPI’s stockholders approved the 2011 ESPP, and it became effective upon the signing of the underwriting agreement related to HPI’s initial public offering in July 2011. HPI reserved a total of 463,352 common stock for issuance under the 2011 ESPP. The 2011 ESPP provided that an additional number of shares would automatically be added to the shares authorized for issuance under the 2011 ESPP each year on January 1, until 2021. The number of shares added each year was equal to the least of: (a) 4% of the total number of common stock outstanding on December 31 of the preceding calendar year; (b) 1,053,074 common stock; or (c) a number of common stock that could be determined each year by HPI’s board of directors that was less than (a) and (b). Subject to certain limitations, HPI’s employees could elect to have 1% to 15% of their compensation withheld through payroll deductions to purchase common stock under the 2011 ESPP at the end of a six-month offering period. Employees purchase common stock at a price per share equal to 85% of the lower of the fair market value at the start or end of the six-month offering period.

On December 5, 2013, pursuant to the terms of the 2011 ESPP, HPI’s board of directors approved an increase in the number of shares available for issuance under the 2011 ESPP of 1,053,074 shares, effective January 1, 2014. As of immediately prior to the closing of the Merger, 614,657 shares had been issued and an aggregate of 1,201,769 common stock were authorized and available for future grants under the 2011 ESPP. Upon consummation of the Merger, the Company assumed the 2011 ESPP.

On May 17, 2014, HPI’s board of directors adopted the Horizon Pharma Public Limited Company 2014 Employee Share Purchase Plan (the “2014 ESPP”). On September 18, 2014, at a special meeting of the stockholders of HPI (the “Special Meeting”), HPI’s stockholders approved the 2014 ESPP. Upon consummation of the Merger, the Company assumed the 2014 ESPP, which served as the successor to the 2011 ESPP. The 2014 ESPP is intended to qualify as an “employee stock purchase plan” within the meaning of section 423 of the Internal Revenue Code of 1986, as amended. The 2014 ESPP provides a means by which employees of the Company (or any eligible subsidiary) may purchase the Company’s ordinary shares through payroll deductions.
Generally, each regular employee (including officers) employed by the Company (or a subsidiary company if the Company’s board of directors designates such company as eligible to participate) will be eligible to participate in offerings under the 2014 ESPP. At the effective time of the 2014 ESPP, 10,201,769 ordinary shares were available for purchase under such plan, which number consisted of 9,000,000 ordinary shares of the Company, plus the 1,201,769 shares remaining available for issuance in the share reserve of the 2011 ESPP as of immediately prior to the effective time of the Merger. The Company’s board of directors may suspend or terminate the 2014 ESPP at any time.

As of December 31, 2014, an aggregate of 9,929,336 ordinary shares were authorized and available for future grants under the 2014 ESPP.

**Stock-Based Compensation Plans**

In October 2005, HPI adopted the 2005 Stock Plan (the “2005 Plan”). The 2005 Plan provided for the granting of stock options to employees and consultants of HPI. Options granted under the 2005 Plan were either incentive stock options or nonqualified stock options. Upon the signing of the underwriting agreement related to HPI’s initial public offering, on July 28, 2011, no further option grants were made under the 2005 Plan. As of July 28, 2011, the 460,842 common stock reserved for future issuance and the 1,304,713 common stock reserved for future issuance upon the exercise of options outstanding under the 2005 Plan were transferred to the 2011 Equity Incentive Plan (the “2011 EIP”), as described below. All stock options granted under the 2005 Plan prior to July 28, 2011 continue to be governed by the terms of the 2005 Plan. Upon consummation of the Merger, the Company assumed the 2005 Plan.

In July 2010, HPI’s board of directors adopted the 2011 EIP. In June 2011, HPI’s stockholders approved the 2011 EIP, and it became effective upon the signing of the underwriting agreement related to HPI’s initial public offering on July 28, 2011. The 2011 EIP had an initial reserve of 3,366,228 common stock, including 460,842 common stock previously reserved for future issuance under the 2005 Plan, 1,304,713 common stock reserved for future issuance upon the exercise of options outstanding under the 2005 Plan as of the 2011 EIP’s effective date and 1,600,673 new common stock reserved. The 2011 EIP provided that an additional number of shares would automatically be added to the shares authorized for issuance each year on January 1, until 2021. The number of shares added each year were equal to the least of: (a) 5% of the total number of common stock outstanding on December 31 of the preceding calendar year; (b) 1,474,304 common stock; or (c) a number of common stock that could be determined each year by HPI’s board of directors that was less than (a) and (b). On December 5, 2013, pursuant to the terms of HPI’s 2011 EIP, HPI’s board of directors approved an increase in the number of shares available for issuance under the 2011 EIP of 1,474,304 shares, effective January 1, 2014. On November 7, 2013, November 16, 2013 and March 3, 2014, HPI’s board of directors approved amendments to the 2011 EIP to reserve an additional 200,000 shares, 800,000 shares and 730,000 shares, respectively, of HPI’s common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of HPI (or following a bona fide period of non-employment with HPI), as an inducement material to the individual’s entry into employment with HPI within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules (“Rule 5635(c)(4)”). On January 10, 2014, HPI’s board of directors approved an amendment to the 2011 EIP to increase the number of shares available for issuance under the 2011 EIP by 703,400 shares (the “January 2014 amendment”), with such increase to the number of shares available for issuance under the 2011 EIP subject to stockholder approval of the January 2014 amendment.

On May 17, 2014, HPI’s board of directors approved an amendment to the 2011 EIP to among other things: increase the aggregate number of shares authorized for issuance under the 2011 EIP by an additional 10,000,000 shares; eliminate the annual “evergreen” provision and require stockholder approval for the issuance of additional shares; and provide that shares reserved as part of the “inducement pool” under Rule 5635(c)(4) may be used for grants to any eligible participant under the 2011 EIP. On June 27, 2014, HPI’s stockholders approved the amendment to the 2011 EIP. As of immediately prior to the closing of the Merger, there were 7,341,996 shares available for future grants under the 2011 EIP. Upon consummation of the Merger, the Company assumed the 2011 EIP.
On May 17, 2014, HPI’s board of directors adopted the Horizon Pharma Public Limited Company 2014 Equity Incentive Plan (the “2014 EIP”) and the Horizon Pharma Public Limited Company 2014 Non-Employee Equity Plan (the “2014 Non-Employee Equity Plan”). At the Special Meeting, HPI’s stockholders approved the 2014 EIP and 2014 Non-Employee Equity Plan. Upon consummation of the Merger, the Company assumed the 2014 EIP and 2014 Non-Employee Equity Plan, which serve as successors to the 2011 EIP.

The 2014 EIP provides for the grant of incentive and nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, other stock awards, and performance awards that may be settled in cash, shares or other property to the employees of the Company (or a subsidiary company). The number of ordinary shares of the Company that are authorized for issuance under the 2014 Plan will be no more than 22,052,130, which number consists of (i) 15,500,000 ordinary shares of the Company; plus (ii) the number of shares available for issuance pursuant to the grant of future awards under the 2011 EIP; plus (iii) any shares subject to outstanding stock awards granted under the 2011 EIP and the 2005 Plan that expire or terminate for any reason prior to exercise or settlement or are forfeited, redeemed or repurchased because of the failure to meet a contingency or condition required to vest such shares; less (iv) 10,000,000 shares, which is the additional number of shares which were previously approved as an increase to the share reserve of the 2011 EIP. The Company’s board of directors has authority to suspend or terminate the 2014 EIP at any time.

The 2014 Non-Employee Equity Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and other forms of stock awards that may be settled in cash, shares or other property to the non-employee directors and consultants of the Company (or a subsidiary company). The total number of ordinary shares of the Company authorized for issuance under the 2014 Non-Employee Equity Plan is 2,500,000. The Company’s board of directors has authority to suspend or terminate the 2014 Non-Employee Equity Plan at any time.

As of December 31, 2014, an aggregate of 14,264,001 ordinary shares were authorized and available for future grants under the 2014 EIP.

### Stock Options

The following table summarizes stock option activity during the year ended December 31, 2014:

<table>
<thead>
<tr>
<th>Options</th>
<th>Weighted Average Exercise Price</th>
<th>Weighted Average Contractual Term</th>
<th>Aggregate Intrinsic Value (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding as of December 31, 2013</td>
<td>Options 4,411,080</td>
<td>$6.47</td>
<td></td>
</tr>
<tr>
<td>Granted</td>
<td>3,902,836</td>
<td>$10.71</td>
<td></td>
</tr>
<tr>
<td>Exercised</td>
<td>(497,082)</td>
<td>$5.27</td>
<td></td>
</tr>
<tr>
<td>Forfeited</td>
<td>(789,151)</td>
<td>$6.16</td>
<td></td>
</tr>
<tr>
<td>Outstanding as of December 31, 2014</td>
<td>7,027,683</td>
<td>$8.95</td>
<td>8.1 years</td>
</tr>
<tr>
<td>Exercisable as of December 31, 2014</td>
<td>2,938,278</td>
<td>$8.71</td>
<td>6.6 years</td>
</tr>
</tbody>
</table>

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The following table summarizes the Company’s outstanding stock options at December 31, 2014:

<table>
<thead>
<tr>
<th>Options Outstanding</th>
<th>Options Exercisable</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exercise Price Ranges</strong></td>
<td><strong>Number of options outstanding</strong></td>
</tr>
<tr>
<td>$1.36 - $3.97</td>
<td>1,574,765</td>
</tr>
<tr>
<td>$4.10 - $5.20</td>
<td>849,484</td>
</tr>
<tr>
<td>$5.21 - $7.47</td>
<td>125,287</td>
</tr>
<tr>
<td>$7.48 - $12.94</td>
<td>3,312,541</td>
</tr>
<tr>
<td>$12.99 - $17.22</td>
<td>915,242</td>
</tr>
<tr>
<td>$20.78 - $28.83</td>
<td>250,364</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>7,027,683</td>
</tr>
</tbody>
</table>

During the years ended December 31, 2014, 2013 and 2012, the Company granted stock options to purchase an aggregate of 3,902,836, 2,158,950 and 516,325 ordinary shares (or prior to the Merger, shares of HPI common stock), respectively, with a weighted average grant date fair value of $10.71, $2.23 and $3.44, respectively.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. The determination of the fair value of each stock option is affected by the Company’s stock price on the date of grant, as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company’s expected stock price volatility over the expected life of the awards and actual and projected stock option exercise behavior. The weighted average fair value per share of stock option awards granted during the years ended December 31, 2014, 2013 and 2012, and assumptions used to value stock options, are as follows:

<table>
<thead>
<tr>
<th>For the Years Ended December 31,</th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dividend yield</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Risk-free interest rate</td>
<td>1.9%</td>
<td>1.2%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Weighted average volatility</td>
<td>83.1%</td>
<td>86.7%</td>
<td>89.0%</td>
</tr>
<tr>
<td>Expected life (in years)</td>
<td>6.11</td>
<td>5.98</td>
<td>5.96</td>
</tr>
<tr>
<td>Weighted average grant date fair value per share of options granted</td>
<td>$8.88</td>
<td>$2.82</td>
<td>$2.50</td>
</tr>
</tbody>
</table>

**Dividend yields**

The Company has never paid dividends and does not anticipate paying any dividends in the near future. Additionally, the Senior Secured Credit Facility contains covenants that restrict the Company from issuing dividends.

**Risk-Free Interest Rate**

The Company determined the risk-free interest rate by using a weighted average assumption equivalent to the expected term based on the U.S. Treasury constant maturity rate as of the date of grant.

**Volatility**

The Company used an average historical stock price volatility of comparable companies to be representative of future stock price volatility, as the Company did not have sufficient trading history for its common stock.
Expected Term

Given the Company’s limited historical exercise behavior, the expected term of options granted was determined using the “simplified” method since the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. Under this approach, the expected term is presumed to be the average of the vesting term and the contractual life of the option.

Forfeitures

As stock-based compensation expense recognized in the consolidated statements of operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures based on actual forfeiture experience, analysis of employee turnover and other factors. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Restricted Stock Units

The following table summarizes restricted stock unit activity for the year ended December 31, 2014:

<table>
<thead>
<tr>
<th>Description</th>
<th>Number of Units</th>
<th>Weighted Average Grant-Date Fair Value Per Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding as of December 31, 2013</td>
<td>833,001</td>
<td>$2.86</td>
</tr>
<tr>
<td>Granted</td>
<td>1,312,722</td>
<td>$10.55</td>
</tr>
<tr>
<td>Vested</td>
<td>(338,520)</td>
<td>$3.89</td>
</tr>
<tr>
<td>Forfeited</td>
<td>(188,701)</td>
<td>$4.73</td>
</tr>
<tr>
<td>Outstanding as of December 31, 2014</td>
<td>1,618,502</td>
<td>$8.66</td>
</tr>
</tbody>
</table>

During the years ended December 31, 2014, 2013 and 2012, the Company granted 1,312,722, 730,000 and 520,000 restricted stock units to acquire shares of the Company’s ordinary shares (or prior to the Merger, shares of HPI common stock) to its employees, respectively. The restricted stock units vest over a four-year period on each anniversary of the vesting commencement date. In December 2013, the Company also granted 101,004 fully vested deferred issuance restricted stock units to the Company’s named executive officers in connection with a one-time bonus payment associated with the completion of the Company’s acquisition of the U.S. rights to VIMOVO.

The following table summarizes share-based compensation expense included in the Company’s consolidated statements of operations for the years ended December 31, 2014, 2013 and 2012 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and development</td>
<td>$1,515</td>
<td>$1,054</td>
<td>$1,186</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>4,174</td>
<td>1,465</td>
<td>1,090</td>
</tr>
<tr>
<td>General and administrative</td>
<td>7,509</td>
<td>2,495</td>
<td>2,385</td>
</tr>
<tr>
<td>Total share-based compensation expense</td>
<td>$13,198</td>
<td>$5,014</td>
<td>$4,661</td>
</tr>
</tbody>
</table>

No income tax benefit has been recognized relating to stock-based compensation expense and no tax benefits have been realized from exercised stock options, due to the Company’s net loss position. As of December 31, 2014, the Company estimates that pre-tax unrecognized compensation expense of $39.1 million for all unvested share-based awards, including both stock options and restricted stock units, will be recognized through the first quarter of 2018. The Company expects to satisfy the exercise of stock options and future distribution of shares of restricted stock by issuing new ordinary shares which have been reserved under the 2014 EIP.
Cash Bonus Program

On November 5, 2014, the compensation committee of the Company’s board of directors approved a performance cash bonus program for the members of the Company’s executive committee and executive leadership team, including its executive officers (the “Cash Bonus Program”). Participants in the Cash Bonus Program will be eligible for a specified cash bonus, the amount of which bonus is determined by whether the Company’s total compounded annualized shareholder rate of return (“TSR”) for the period from November 5, 2014 to May 6, 2015 is greater than or equal to a specified threshold that ranges between 15% and 60%, and which bonus will be earned and payable only if the TSR for the period from November 5, 2014 to November 4, 2017 is greater than 15%. The TSR for these periods will be calculated using the 20-day volume weighted average trading price of the Company’s ordinary shares. The total bonus pool that may be payable under the Cash Bonus Program will be calculated as of May 6, 2015 and may range from $4.5 million to $17.0 million, depending upon the TSR for the period from November 5, 2014 to May 6, 2015. The portion of the total bonus pool payable to individual participants will be based on pre-determined allocations established by the Company’s compensation committee. Participants must remain employed by the Company through November 4, 2017 unless a participant’s earlier departure from employment is due to death, disability, termination without cause or a change in control transaction, to be further defined in a written plan. Bonus payments under the Cash Bonus Program, if any, will be made after November 4, 2017.

The Company accounts for the Cash Bonus Program under the liability method in accordance with ASC Topic 718, Compensation–Stock Compensation. Because the value of the Cash Bonus Program pool is dependent upon the attainment of a target level of TSR, it requires the impact of the market condition to be considered when estimating the fair value of the bonus pool. As a result, the Monte Carlo model is applied and $1.6 million was estimated to be the fair value of the award. As of December 31, 2014, the Company recorded $0.1 million of expense related to the Cash Bonus Program.

NOTE 19 – RELATED PARTY TRANSACTIONS

On June 17, 2014, Mr. Robert De Vaere entered into an executive employment and transition agreement with the Company (the “Transition Agreement”), as part of his transition as the Company’s then current Executive Vice President and Chief Financial Officer, to a consulting position. Pursuant to the Transition Agreement Mr. De Vaere (a) continued to serve as the Company’s Executive Vice President and Chief Financial Officer through September 30, 2014, (b) will serve as a consultant to the Company for a fee of $50,000 per month from October 1, 2014 through March 31, 2015, and (c) will serve as a consultant to the Company in a reduced capacity for a fee of $20,000 per month from April 1, 2015 through September 30, 2015.

In connection with the Merger, the Company entered into an amendment to the employment agreement with Dr. Virinder Nohria, one of its directors. Pursuant to the amendment to the employment agreement, Dr. Nohria’s employment with Vidara was terminated, and Dr. Nohria received a $0.5 million lump sum payment that was contingent on his execution of a general release of claims. The Company also entered into a consulting agreement with Dr. Nohria. Pursuant to the consulting agreement, Dr. Nohria has been retained as a consultant by the Company for a term of one year, and is being paid $10,000 per month of service as a consultant.

In November 2014, certain of our shareholders, including Dr. Nohria and an affiliated trust, sold a number of Horizon Pharma plc ordinary shares in an underwritten public offering. As part of the offering, the Company agreed to reimburse Dr. Nohria and his affiliated trust, as well as another selling shareholder, for certain of the underwriting discounts otherwise payable by them in the offering. Based upon the sale by Dr. Nohria and his affiliated trust of an aggregate of 2,784,512 shares in the offering, the Company reimbursed Dr. Nohria and his affiliated trust a total of approximately $0.7 million.

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NOTE 20 – INCOME TAXES

The Company’s loss before benefit for income taxes by jurisdiction for the years ended December 31, 2014, 2013 and 2012 is as follows (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ireland</td>
<td>$22,164</td>
<td>$—</td>
<td>$—</td>
</tr>
<tr>
<td>United States</td>
<td>$(275,080)</td>
<td>$(139,347)</td>
<td>56,038</td>
</tr>
<tr>
<td>Other Foreign</td>
<td>(16,771)</td>
<td>(10,779)</td>
<td>(149,003)</td>
</tr>
<tr>
<td>Loss before benefit for income taxes</td>
<td>$(269,687)</td>
<td>$(150,126)</td>
<td>$(92,965)</td>
</tr>
</tbody>
</table>

The components of the benefit for income taxes were as follows for the years ended December 31, 2014, 2013 and 2012 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current provision</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td>$—</td>
<td>$—</td>
<td>$—</td>
</tr>
<tr>
<td>US - Federal and State</td>
<td>815</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Other Foreign</td>
<td>55</td>
<td>43</td>
<td>35</td>
</tr>
<tr>
<td>Total current provision</td>
<td>870</td>
<td>47</td>
<td>39</td>
</tr>
<tr>
<td>Deferred benefit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td>$—</td>
<td>$—</td>
<td>$—</td>
</tr>
<tr>
<td>US - Federal and State</td>
<td>(3,860)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Other Foreign</td>
<td>(3,094)</td>
<td>(1,168)</td>
<td>(5,210)</td>
</tr>
<tr>
<td>Total deferred benefit</td>
<td>(6,954)</td>
<td>(1,168)</td>
<td>(5,210)</td>
</tr>
<tr>
<td>Loss before benefit for income taxes</td>
<td>$(6,084)</td>
<td>$(1,121)</td>
<td>$(5,171)</td>
</tr>
</tbody>
</table>

Total benefit for income taxes was $6.1 million, $1.1 million and $5.2 million for the years ended December 31, 2014, 2013 and 2012, respectively. Current expense of $0.9 million for the year ended December 31, 2014 consisted primarily of alternative minimum tax. During the year ended December 31, 2014, the Company released a portion of its valuation allowance as a result of the Merger. In connection with the Merger, the Company recorded additional deferred tax liabilities related to certain acquired assets. Accordingly, the Company recorded a net benefit for income taxes of $3.0 million for the release of its valuation allowance during the third quarter of 2014. In addition, the Company eliminated its deferred tax liability of $3.0 million at its Swiss subsidiary related to the intercompany sale of intellectual property in the fourth quarter of 2014. As a result, the Company recorded an overall deferred tax benefit for income taxes of $7.0 million, including the net effect of other deferred tax items, during the year ended December 31, 2014.

During the year ended December 31, 2014, the Company recorded a $215.0 million loss on the derivative revaluation in connection with the increase in the fair value of the embedded derivative associated with the Convertible Senior Notes. The loss on derivative revaluation was a permanent tax difference and is not deductible for income tax reporting purposes. At the end of the third quarter of 2014, the capped call related to the $150.0 million convertible debt was removed resulting in revaluation of the debt for tax purposes. As a result of the debt revaluation (for tax purposes only), it was determined that an additional $22.8 million of interest expense could be claimed. During the fourth quarter of 2014, $89.1 million of the $150.0 million of convertible debt was converted resulting in a book loss on conversion of $29.4 million. The net result of the convertible debt settlements was that $14.7 million of the additional interest expense is deductible as a permanent item and $8.1 million as a temporary item for tax purposes.

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The $6.1 million increase in the income tax benefit during the year ended December 31, 2014 related primarily to the recognition of the effect of the Merger acquisition liabilities recorded in the third quarter of 2014 for $3.0 million and the elimination of the deferred tax liability due to the intercompany sale of intellectual property in the fourth quarter of 2014 for $3.0 million. The $4.1 million decrease in the income tax benefit during the year ended December 31, 2013 was primarily attributable to the absence of one-time tax benefits in 2013 that were recorded during 2012.

As a result of the Merger in the third quarter of 2014, the Company changed its status from a U.S. company to an Irish company. Consequently, the controlling statutory income tax rate with respect to the effective income tax rate analysis is a 12.5% corporate tax rate for an Irish trading company versus the U.S. corporate rate of 35%.

A reconciliation between the Irish rate for 2014 and the U.S. federal statutory income tax rate for 2013 and 2012, respectively, and the Company’s effective tax is as follows (in thousands):

<table>
<thead>
<tr>
<th>For the Years Ended December 31,</th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irish income tax statutory rate (12.5%)</td>
<td>$(33,711)</td>
<td>$ —</td>
<td>$ —</td>
</tr>
<tr>
<td>US federal income tax at statutory rate (35%)</td>
<td>—</td>
<td>$(52,543)</td>
<td>$(32,538)</td>
</tr>
<tr>
<td>Bargain purchase gain</td>
<td>(5,542)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Transaction costs</td>
<td>5,402</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Excise tax</td>
<td>3,911</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Stock based compensation</td>
<td>1,460</td>
<td>1,107</td>
<td>1,063</td>
</tr>
<tr>
<td>Foreign tax rate differential</td>
<td>(64,675)</td>
<td>2,019</td>
<td>4,376</td>
</tr>
<tr>
<td>Deferred taxes not benefited</td>
<td>7,360</td>
<td>23,921</td>
<td>21,715</td>
</tr>
<tr>
<td>Derivative liability</td>
<td>75,248</td>
<td>24,255</td>
<td>—</td>
</tr>
<tr>
<td>Notional interest deduction</td>
<td>(2,149)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Interest expense on convertible debt inducements</td>
<td>(4,789)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Book loss on debt extinguishment</td>
<td>10,286</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Other</td>
<td>1,115</td>
<td>120</td>
<td>213</td>
</tr>
<tr>
<td>Income tax benefit</td>
<td>$(6,084)</td>
<td>$(1,121)</td>
<td>$(5,171)</td>
</tr>
<tr>
<td>Effective income tax rate</td>
<td>-2.26%</td>
<td>-10.39%</td>
<td>34.70%</td>
</tr>
</tbody>
</table>

No provision has been made for income taxes on undistributed earnings of foreign subsidiaries because it is the Company’s intention to indefinitely reinvest undistributed earnings of its foreign subsidiaries. There are no material undistributed foreign earnings. In the event of the distribution of those earnings in the form of dividends, a sale of the subsidiaries, or certain other transactions, the Company may be liable for income taxes. As of December 31, 2014, it was not practicable to determine the amount of the income tax liability related to those investments.

The Company accounts for income taxes based upon an asset and liability approach. Deferred tax assets and liabilities represent the future tax consequences of the differences between the financial statement carrying amounts of assets and liabilities versus the tax basis of assets and liabilities. Under this method, deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The impact of tax rate changes on deferred tax assets and liabilities is recognized in the year that the change is enacted.
The tax effects of the temporary differences and net operating losses that give rise to significant portions of deferred tax assets and liabilities are as follows (in thousands):

<table>
<thead>
<tr>
<th>Deferred tax assets:</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net operating and capital loss carry forwards</td>
<td>$105,182</td>
<td>$121,001</td>
</tr>
<tr>
<td>Alternative minimum tax credit</td>
<td>$820</td>
<td>—</td>
</tr>
<tr>
<td>Derivative liability</td>
<td>—</td>
<td>14,799</td>
</tr>
<tr>
<td>Accrued compensation</td>
<td>6,397</td>
<td>—</td>
</tr>
<tr>
<td>Accruals and reserves</td>
<td>4,952</td>
<td>7,073</td>
</tr>
<tr>
<td>Original issuance discount related to capped call</td>
<td>—</td>
<td>6,740</td>
</tr>
<tr>
<td>Contingent royalties</td>
<td>14,495</td>
<td>3,122</td>
</tr>
<tr>
<td>Research and development credits</td>
<td>—</td>
<td>2,571</td>
</tr>
<tr>
<td>Foreign intangible assets</td>
<td>—</td>
<td>63</td>
</tr>
<tr>
<td><strong>Total deferred tax assets</strong></td>
<td><strong>131,846</strong></td>
<td><strong>155,369</strong></td>
</tr>
<tr>
<td>Valuation allowance</td>
<td>(111,555)</td>
<td>(128,422)</td>
</tr>
<tr>
<td><strong>Deferred tax assets, net of valuation allowance</strong></td>
<td><strong>20,291</strong></td>
<td><strong>26,947</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deferred tax liabilities:</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acquisition liabilities</td>
<td>$3,068</td>
<td>$14,477</td>
</tr>
<tr>
<td>Debt discount</td>
<td>4,791</td>
<td>—</td>
</tr>
<tr>
<td>Interest expense on convertible debt inducements</td>
<td>3,306</td>
<td>—</td>
</tr>
<tr>
<td>In-process research and development</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Developed technology</td>
<td>—</td>
<td>13,009</td>
</tr>
<tr>
<td>Intangible assets</td>
<td>7,137</td>
<td>2,823</td>
</tr>
<tr>
<td>Other</td>
<td>1,989</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total deferred tax liabilities</strong></td>
<td><strong>20,291</strong></td>
<td><strong>30,309</strong></td>
</tr>
</tbody>
</table>

**Net deferred income tax liability** | **$3,362** |

The decrease in the deferred tax valuation allowance was $16.9 million for the year ended December 31, 2014 and the increase in the valuation allowance was $32.5 million and $27.8 million for the years ended December 31, 2013 and 2012, respectively. The decrease in the deferred tax valuation allowance in 2014 was due primarily to the utilization of net operating losses in the United States and the release of allowances as a result of acquired Merger liabilities and the intercompany asset sale noted above. The increase in the deferred tax valuation allowance in 2013 was primarily the result of higher federal and state net operating losses, which were fully reserved for due to the uncertainty surrounding the realization of these assets. A reconciliation of the beginning and ending amounts of the valuation allowance for the years ended December 31, 2014 and 2013 are as follows (in thousands):

| Valuation allowance at December 31, 2012 | $ (95,970) |
| Increase for current year activity | (32,452) |
| Valuation allowance at December 31, 2013 | $(128,422) |
| Decrease for current year activity | $ 9,507 |
| Release in valuation allowance | 7,360 |
| Valuation allowance at December 31, 2014 | $(111,555) |

As of December 31, 2014, the Company had net operating loss carryforwards of approximately $240.0 million, $55.0 million and $103.0 million available to reduce future taxable income, if any, for federal, state, and
foreign income tax purposes, respectively. Net operating loss carryforwards for federal income tax purposes will begin to expire in 2027. State net operating losses expire approximately within the same time period as the federal losses. Foreign net operating losses expire beginning in 2015. Utilization of the net operating loss carryforwards may be subject to annual limitations as prescribed by federal and state statutory provisions. The annual limitation may result in the expiration of net operating loss carryforwards prior to their utilization.

As of December 31, 2014 and 2013, the Company had research and development credit carryforwards for federal and state income tax purposes of approximately $2.7 million and $0.4 million, respectively, available to reduce future taxable income. In 2014, the Company determined it is more likely than not that these credits will not be utilized. Accordingly, the deferred tax assets and the related ASC 740-10 reserve of $0.5 million was reversed.

The Company accounts for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on an income tax return. The changes in the Company’s uncertain income tax positions for the years ended December 31, 2014, 2013 and 2012 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th>For the Years Ended December 31,</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning balance</td>
<td>$ 491</td>
<td>$442</td>
</tr>
<tr>
<td>Tax positions related to current year:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additions</td>
<td>775</td>
<td>51</td>
</tr>
<tr>
<td>Reductions</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>775</td>
<td>51</td>
</tr>
<tr>
<td>Tax positions related to prior years:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additions</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Reductions</td>
<td>(491)</td>
<td>(2)</td>
</tr>
<tr>
<td>Settlements</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Lapses in statutes of limitations</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Additions from current year acquisitions</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>(491)</td>
<td>(2)</td>
</tr>
<tr>
<td>Ending balance</td>
<td>$ 775</td>
<td>$491</td>
</tr>
</tbody>
</table>

As a result of the Merger, the Company acquired $0.8 million in ASC 740-10 liability with respect to net operating loss carryovers. Further, as noted above, the Company abandoned its claim for research and development tax credit carryovers and, accordingly, reversed the ASC 740-10 reserve of $0.5 million set up in prior years.

The Company has assessed that its liability for unrecognized income tax benefits will not significantly change within the next twelve months. If these unrecognized tax benefits are recognized, the impact on the Company’s effective tax rate would be immaterial. Additionally, there was no interest or penalties accrued at December 31, 2014 and 2013, respectively, due to the Company’s net operating loss position.

The Company files income tax returns in the U.S. federal and in various state and foreign jurisdictions. At December 31, 2014, all open tax years in the federal and some state jurisdictions date back to 2005 due to the taxing authorities’ ability to adjust operating loss carryforwards. No changes in settled tax years have occurred through December 31, 2014 and the Company does not anticipate there will be a material change in the total amount of unrecognized tax benefits within the next 12 months.
The Company realized no income tax benefit from stock option exercises in each of the periods presented in these financial statements due to recurring losses and valuation allowances. As of December 31, 2014, the Company had $0.3 million of total unrecognized compensation expense.

The Company classifies interest and penalties with respect to income tax liabilities as a component of income tax expense.

NOTE 21 – EMPLOYEE BENEFIT PLANS

The Company sponsors a defined contribution 401(k) retirement savings plan covering all of its U.S. employees, whereby an eligible employee may elect to contribute a portion of his or her salary on a pre-tax basis, subject to applicable federal limitations. The Company is not required to make any discretionary matching of employee contributions. Beginning in 2014, the Company made a matching contribution generally equal to 50% of each employee’s elective contribution to the plan of up to six percent of the employee’s eligible pay with a 20% graded vesting over five years. For the years ended December 31, 2014, the Company recorded defined contribution expense of $0.8 million and for the years ended December 31, 2013 and 2012, the Company did not record any expense under the plan.

The Company’s wholly-owned subsidiary, Horizon Pharma AG, sponsors a defined benefit savings plan covering all of its employees in Switzerland and a defined contribution plan for its employees in Germany. For the years ended December 31, 2014, 2013 and 2012, the Company recognized expenses of $0.1 million each, under these plans.

NOTE 22 – SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table provides a summary of selected financial results of operations by quarter for the years ended December 31, 2014 and 2013 (in thousands, except per share data):

<table>
<thead>
<tr>
<th>Year</th>
<th>First</th>
<th>Second</th>
<th>Third</th>
<th>Fourth</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>Net sales</td>
<td>$51,926</td>
<td>$66,062</td>
<td>$75,126</td>
</tr>
<tr>
<td></td>
<td>Gross profit</td>
<td>44,307</td>
<td>41,252</td>
<td>61,482</td>
</tr>
<tr>
<td></td>
<td>Gain (loss) from operations</td>
<td>1,587</td>
<td>(7,100)</td>
<td>(11,961)</td>
</tr>
<tr>
<td></td>
<td>Net (loss) income</td>
<td>(206,250)</td>
<td>(27,769)</td>
<td>2,063</td>
</tr>
<tr>
<td></td>
<td>Net (loss) income per ordinary share-basic and diluted</td>
<td>$(-3.07)</td>
<td>$(-0.38)</td>
<td>$0.03</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>First</th>
<th>Second</th>
<th>Third</th>
<th>Fourth</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>Net sales</td>
<td>$8,693</td>
<td>$11,131</td>
<td>$24,112</td>
</tr>
<tr>
<td></td>
<td>Gross profit</td>
<td>4,924</td>
<td>8,737</td>
<td>20,905</td>
</tr>
<tr>
<td></td>
<td>Loss from operations</td>
<td>(18,544)</td>
<td>(15,804)</td>
<td>(2,744)</td>
</tr>
<tr>
<td></td>
<td>Net loss</td>
<td>(22,171)</td>
<td>(18,441)</td>
<td>(5,492)</td>
</tr>
<tr>
<td></td>
<td>Net loss per ordinary share-basic and diluted</td>
<td>$(-0.36)</td>
<td>$(-0.29)</td>
<td>$(-0.08)</td>
</tr>
</tbody>
</table>
Report of Independent Registered Public Accounting Firm on
Financial Statement Schedule

To the Board of Directors
of Horizon Pharma plc:

Our audits of the consolidated financial statements and of the effectiveness of internal control over financial reporting referred to in our report dated February 27, 2015 appearing in the 2015 Annual Report to Shareholders of Horizon Pharma plc (which report and consolidated financial statements are incorporated by reference in this Annual Report on Form 10-K) also included an audit of the financial statement schedule listed in Item 15(a)(2) of this Form 10-K. In our opinion, this financial statement schedule presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements.

/s/ PricewaterhouseCoopers LLP
Chicago, Illinois
February 27, 2015
### HORIZON PHARMA PLC

**SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS**

For Each of the Three Fiscal Years Ended December 31, 2014, 2013 and 2012:

<table>
<thead>
<tr>
<th>Valuation and Qualifying Accounts</th>
<th>Balance at beginning of period</th>
<th>Additions charged to costs and expenses</th>
<th>Deductions from reserves</th>
<th>Balance at end of period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allowance for discounts and returns</td>
<td>$431</td>
<td>18,254</td>
<td>(14,202)</td>
<td>$4,483</td>
</tr>
<tr>
<td>Deferred tax asset valuation allowance</td>
<td>$128,422</td>
<td>—</td>
<td>(16,867)</td>
<td>$111,555</td>
</tr>
<tr>
<td><strong>Year ended December 31, 2014:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allowance for discounts and returns</td>
<td>$77</td>
<td>3,270</td>
<td>(2,916)</td>
<td>$431</td>
</tr>
<tr>
<td>Deferred tax asset valuation allowance</td>
<td>$95,970</td>
<td>32,452</td>
<td>—</td>
<td>$128,422</td>
</tr>
<tr>
<td><strong>Year ended December 31, 2013:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allowance for discounts and returns</td>
<td>$170</td>
<td>365</td>
<td>(458)</td>
<td>$77</td>
</tr>
<tr>
<td>Deferred tax asset valuation allowance</td>
<td>$68,194</td>
<td>32,034</td>
<td>(4,258)</td>
<td>$95,970</td>
</tr>
</tbody>
</table>
## INDEX TO EXHIBITS

<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description of Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1(15)</td>
<td>Transaction Agreement and Plan of Merger, dated March 18, 2014, by and among Horizon Pharma, Inc., Valens Therapeutics Holdings LLC, Valens Therapeutics International Ltd (now known as Horizon Pharma Public Limited Company), Hamilton Holdings (USA), Inc. and Hamilton Merger Sub, Inc.†</td>
</tr>
<tr>
<td>2.2(17)</td>
<td>First Amendment to Transaction Agreement and Plan of Merger, dated June 12, 2014, by and between Horizon Pharma, Inc. and Valens Therapeutics Holdings LLC.</td>
</tr>
<tr>
<td>3.1(20)</td>
<td>Memorandum and Articles of Association of Horizon Pharma Public Limited Company.</td>
</tr>
<tr>
<td>4.1(1)***</td>
<td>Warrant issued by Horizon Pharma, Inc. on December 18, 2007 to Comerica Bank.</td>
</tr>
<tr>
<td>4.2(1)***</td>
<td>Warrant issued by Horizon Pharma, Inc. on December 18, 2007 to Hercules Technology Growth Capital, Inc.</td>
</tr>
<tr>
<td>4.3(1)***</td>
<td>Warrant issued by Horizon Pharma, Inc. on November 21, 2008 to Comerica Bank.</td>
</tr>
<tr>
<td>4.4(1)***</td>
<td>Warrant issued by Horizon Pharma, Inc. on November 21, 2008 to Hercules Technology Growth Capital, Inc.</td>
</tr>
<tr>
<td>4.5(3)***</td>
<td>Form of Warrant issued by Horizon Pharma, Inc. pursuant to the Securities Purchase Agreement, dated February 28, 2012, by and among Horizon Pharma, Inc. and the Purchasers and Warrant Holders listed therein.</td>
</tr>
<tr>
<td>4.6(6)***</td>
<td>Form of Warrant issued by Horizon Pharma, Inc. in Public Offering of Units.</td>
</tr>
<tr>
<td>4.7(12)</td>
<td>Indenture, dated as of November 22, 2013, by and between Horizon Pharma, Inc. and U.S. Bank National Association.</td>
</tr>
<tr>
<td>4.9(12)</td>
<td>Registration Rights Agreement, dated September 1, 2014, by and among Valens Therapeutics International Ltd (now known as Horizon Pharma Public Limited Company), Valens Therapeutics Holdings LLC and certain shareholders of Valens Therapeutics International Ltd.</td>
</tr>
<tr>
<td>10.1(20)</td>
<td>Form of Indemnification Agreement entered into by and between Horizon Pharma Public Limited Company and certain directors, officers and employees.</td>
</tr>
<tr>
<td>10.2(20)</td>
<td>Form of Indemnification Agreement entered into by and between Horizon Pharma, Inc. and certain directors, officers and employees of Horizon Pharma Public Limited Company.</td>
</tr>
<tr>
<td>10.3+(20)</td>
<td>Horizon Pharma Public Limited Company Non-Employee Director Compensation Policy.</td>
</tr>
<tr>
<td>10.4+(1)***</td>
<td>Horizon Pharma, Inc. 2005 Stock Plan and Form of Stock Option Agreement thereunder.</td>
</tr>
<tr>
<td>10.5+(11)***</td>
<td>Horizon Pharma, Inc. 2011 Equity Incentive Plan, as amended, and Form of Option Agreement and Form of Stock Option Grant Notice thereunder.</td>
</tr>
<tr>
<td>10.6+(11)***</td>
<td>Horizon Pharma, Inc. 2011 Employee Stock Purchase Plan and Form of Offering Document thereunder.</td>
</tr>
<tr>
<td>10.7+(21)</td>
<td>Horizon Pharma Public Limited Company 2014 Non-Employee Equity Incentive Plan and Form of Option Agreement, Form of Stock Option Grant Notice, Form of Restricted Stock Unit Agreement and Form of Restricted Stock Unit Grant Notice thereunder.</td>
</tr>
<tr>
<td>10.8+(21)</td>
<td>Horizon Pharma Public Limited Company 2014 Non-Employee Equity Incentive Plan and Form of Option Agreement, Form of Stock Option Grant Notice, Form of Restricted Stock Unit Agreement and Form of Restricted Stock Unit Grant Notice thereunder.</td>
</tr>
</tbody>
</table>
Horizon Pharma Public Limited Company 2014 Employee Share Purchase Plan.

10.9+(21) Development and License Agreement, dated August 20, 2004, by and among Horizon Pharma AG, Jagotec AG and SkyPharma AG.

10.10*(1) Amendment to Development and License Agreement, dated August 5, 2007, by and among Horizon Pharma AG, Jagotec AG and SkyPharma AG.

10.12*(1) Manufacturing and Supply Agreement, dated August 3, 2007, by and between Horizon Pharma AG and Jagotec AG.

10.15*(1) Transfer, License and Supply Agreement, dated December 21, 2006, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck Serono GmbH (which was subsequently assigned to Mundipharma Laboratories GmbH in April 2011).

10.16*(1) Transfer, License and Supply Agreement, dated December 17, 2008, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck Serono GmbH (which was subsequently assigned to Mundipharma Laboratories GmbH in April 2011).

10.17+(1) Form of Employee Proprietary Information and Inventions Agreement.

10.18*(1) Manufacturing and Supply Agreement, dated March 24, 2009, by and between Horizon Pharma AG and Mundipharma Medical Company.


10.20(1) Amendment to Exclusive Distribution Agreement, dated July 7, 2009, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.


10.23*(1) Amendment to Manufacturing and Supply Agreement, dated March 4, 2011, by and between Horizon Pharma AG and Jagotec AG.

10.24(1) Manufacturing and Supply Agreement, dated May 25, 2011, by and between Horizon Pharma USA, Inc. and sanofi-aventis U.S. LLC.

10.25*(1) Sales Contract, dated July 1, 2010, by and between Horizon Pharma USA, Inc. and BASF Corporation.

10.26(1) Manufacturing and Supply Agreement, dated November 4, 2010 by and between Horizon Pharma AG and Mundipharma Medical Company.


10.29(10) Amendment to Manufacturing and Supply Agreement, effective as of September 25, 2013, by and between Horizon Pharma USA, Inc. and sanofi-aventis U.S. LLC.
<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description of Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.30*(2)</td>
<td>Standard Office Lease, effective August 31, 2011, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.</td>
</tr>
<tr>
<td>10.31(9)</td>
<td>Letter Agreement, dated October 17, 2012, by and among Horizon Pharma AG, Mundipharma International Corporation Limited and Mundipharma Medical Company.</td>
</tr>
<tr>
<td>10.33*(4)</td>
<td>Amendment No. 1 to Exclusive Distribution Agreement, dated March 5, 2012, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.</td>
</tr>
<tr>
<td>10.34(4)</td>
<td>Amendment No. 1 to Manufacturing and Supply Agreement, dated March 5, 2012, by and between Horizon Pharma AG and Mundipharma Medical Company.</td>
</tr>
<tr>
<td>10.36*(7)</td>
<td>First Amendment to Lease, dated July 31, 2012, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.</td>
</tr>
<tr>
<td>10.37*(14)</td>
<td>Second Amendment to Lease, dated December 10, 2013, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.</td>
</tr>
<tr>
<td>10.38*(19)</td>
<td>Third Amendment to Lease, dated June 30, 2014, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.</td>
</tr>
<tr>
<td>10.40*(14)</td>
<td>Amendment No. 2 to Exclusive Distribution Agreement, dated October 25, 2013, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.</td>
</tr>
<tr>
<td>10.41(14)</td>
<td>Amendment No. 2 to Manufacturing and Supply Agreement, dated October 25, 2013, by and between Horizon Pharma AG and Mundipharma Medical Company.</td>
</tr>
<tr>
<td>10.44*(16)</td>
<td>Asset Purchase Agreement, dated November 18, 2013, by and between Horizon Pharma USA, Inc. and AstraZeneca AB.</td>
</tr>
<tr>
<td>10.45*(16)</td>
<td>License Agreement, dated November 22, 2013, by and between Horizon Pharma USA, Inc. and AstraZeneca AB.</td>
</tr>
<tr>
<td>10.46*(16)</td>
<td>Amended and Restated Collaboration and License Agreement for the United States, dated November 18, 2013, by and between Horizon Pharma USA, Inc. and POZEN Inc.</td>
</tr>
<tr>
<td>10.47*(14)</td>
<td>Amendment No. 1 to Amended and Restated Collaboration and License Agreement for the United States, dated November 18, 2013, by and between Horizon Pharma USA, Inc. and POZEN Inc.</td>
</tr>
<tr>
<td>10.48*(14)</td>
<td>Letter Agreement, dated November 18, 2013, by and among Horizon Pharma USA, Inc., AstraZeneca AB and POZEN Inc.</td>
</tr>
<tr>
<td>10.49*(16)</td>
<td>Master Manufacturing Services Agreement, dated October 31, 2013, by and between Horizon Pharma, Inc. and Patheon Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>10.50+(13)</td>
<td>First Amendment to Amended and Restated Executive Employment Agreement, dated January 16, 2014, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Timothy P. Walbert.</td>
</tr>
<tr>
<td>Exhibit Number</td>
<td>Description of Document</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>10.51+(13)</td>
<td>First Amendment to Amended and Restated Executive Employment Agreement, dated January 16, 2014, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Jeffrey W. Sherman, M.D., FACP.</td>
</tr>
<tr>
<td>10.52+(14)</td>
<td>Executive Employment Agreement, effective March 5, 2014, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Robert F. Carey.</td>
</tr>
<tr>
<td>10.54+(17)</td>
<td>Executive Employment Agreement, effective June 23, 2014, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Paul W. Hoelscher.</td>
</tr>
<tr>
<td>10.55(18)</td>
<td>Credit Agreement, dated June 17, 2014, by and among Horizon Pharma, Inc., as initial signatory, the lenders party thereto and Citibank N.A., as administrative agent and collateral agent.</td>
</tr>
<tr>
<td>10.56(22)</td>
<td>Asset Purchase Agreement, dated October 17, 2014, by and between Horizon Pharma Public Limited Company and Novo Research Inc.</td>
</tr>
<tr>
<td>10.57(22)</td>
<td>Supply Agreement, dated October 17, 2014, by and between Horizon Pharma Public Limited Company and Novo Research Inc.</td>
</tr>
<tr>
<td>10.59</td>
<td>Amendment to Asset Purchase Agreement, dated July 31, 2015, by and between Vidara Therapeutics Research Limited and InterMune, Inc.</td>
</tr>
<tr>
<td>10.60</td>
<td>Amendment to Asset Purchase Agreement, dated June 18, 2012, by and among Vidara Therapeutics International Public Limited Company, Vidara Therapeutics Holdings LLC, Vidara Therapeutics Research Limited and InterMune, Inc.</td>
</tr>
<tr>
<td>10.61*</td>
<td>Consolidated Supply Agreement, dated July 31, 2015, by and between Vidara Therapeutics Research Limited and Boehringer Ingelheim RCV GmbH &amp; Co KG.</td>
</tr>
<tr>
<td>10.64*</td>
<td>Amendment No. 2 to License Agreement for Interferon Gamma, dated January 15, 1999, by and between Genentech, Inc. and Connetics Corporation.</td>
</tr>
<tr>
<td>10.65*</td>
<td>Amendment No. 3 to License Agreement for Interferon Gamma, dated April 27, 1999, by and between Genentech, Inc. and Connetics Corporation.</td>
</tr>
<tr>
<td>10.66</td>
<td>Consent to Assignment Agreement, dated June 23, 2000 (Amendment No. 4), by and among Genentech, Inc., Connetics Corporation and InterMune Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>10.67</td>
<td>Amendment No. 5 to License Agreement for Interferon Gamma, dated January 25, 2001, by and between Genentech, Inc. and InterMune Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>10.68*</td>
<td>Amendment No. 6 to License Agreement for Interferon Gamma, dated February 27, 2006, by and between Genentech, Inc. and InterMune, Inc.</td>
</tr>
<tr>
<td>10.69*</td>
<td>Amendment No. 7 to License Agreement for Interferon Gamma, dated December 17, 2015, by and between Genentech, Inc. and Vidara Therapeutics International Public Limited Company.</td>
</tr>
<tr>
<td>10.70</td>
<td>Assignment and Option Agreement, dated June 21, 2000, by and between Connetics Corporation and InterMune Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>Exhibit Number</td>
<td>Description of Document</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>10.71</td>
<td>Revenue Adjustment Agreement, dated June 27, 2000, by and between InterMune Pharmaceuticals, Inc. and Connetics Corporation.</td>
</tr>
<tr>
<td>10.73†</td>
<td>Consulting Agreement, dated March 18, 2014 between Horizon Pharma USA, Inc. and Virinder Nohria.</td>
</tr>
<tr>
<td>10.74†</td>
<td>Executive Employment Agreement, effective September 18, 2014, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Barry Moze.</td>
</tr>
<tr>
<td>10.75†</td>
<td>Executive Employment Agreement, effective November 24, 2014, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and John Kody.</td>
</tr>
<tr>
<td>10.76†</td>
<td>Horizon Pharma Public Limited Company Cash Long Term Incentive Program.</td>
</tr>
<tr>
<td>10.77**</td>
<td>Amendment No. 3 to Exclusive Distribution Agreement, dated September 22, 2014, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.</td>
</tr>
<tr>
<td>10.78</td>
<td>Amendment No. 3 to Manufacturing and Supply Agreement, dated September 22, 2014, by and between Horizon Pharma AG and Mundipharma Medical Company.</td>
</tr>
<tr>
<td>21.1</td>
<td>Subsidiaries of Horizon Pharma Public Limited Company.</td>
</tr>
<tr>
<td>23.1</td>
<td>Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.</td>
</tr>
<tr>
<td>24.1</td>
<td>Power of Attorney. Reference is made to the signature page hereto.</td>
</tr>
<tr>
<td>31.1</td>
<td>Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.</td>
</tr>
<tr>
<td>31.2</td>
<td>Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.</td>
</tr>
<tr>
<td>32.1</td>
<td>Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.</td>
</tr>
<tr>
<td>32.2</td>
<td>Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.</td>
</tr>
<tr>
<td>101.INS</td>
<td>XBRL Instance Document</td>
</tr>
<tr>
<td>101.SCH</td>
<td>XBRL Taxonomy Extension Schema Document</td>
</tr>
<tr>
<td>101.CAL</td>
<td>XBRL Taxonomy Extension Calculation Linkbase Document</td>
</tr>
<tr>
<td>101.DEF</td>
<td>XBRL Taxonomy Extension Definition Linkbase Document</td>
</tr>
<tr>
<td>101.LAB</td>
<td>XBRL Taxonomy Extension Label Linkbase Document</td>
</tr>
<tr>
<td>101.PRE</td>
<td>XBRL Taxonomy Extension Presentation Linkbase Document</td>
</tr>
</tbody>
</table>

+ Indicates management contract or compensatory plan. |
† Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Horizon Pharma Public Limited Company undertakes to furnish supplemental copies of any of the omitted schedules upon request by the Securities and Exchange Commission. |
* Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission. |
** Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission. |
*** Indicates an instrument, agreement or compensatory arrangement or plan assumed by Horizon Pharma Public Limited Company in the merger and no longer binding on Horizon Pharma, Inc.
Table of Contents

(1) Incorporated by reference to Horizon Pharma, Inc.’s Registration Statement on Form S-1 (No. 333-168504), as amended.
(2) Incorporated by reference to Horizon Pharma, Inc.’s Quarterly Report on Form 10-Q, filed on November 14, 2011.
(3) Incorporated by reference to Horizon Pharma, Inc.’s Current Report on Form 8-K, filed on March 1, 2012.
(7) Incorporated by reference to Horizon Pharma, Inc.’s Quarterly Report on Form 10-Q, filed on November 13, 2012.
(9) Incorporated by reference to Horizon Pharma, Inc.’s Quarterly Report on Form 10-Q, filed on May 10, 2013.
(10) Incorporated by reference to Horizon Pharma, Inc.’s Quarterly Report on Form 10-Q, filed on November 8, 2013.
(16) Incorporated by reference to Horizon Pharma, Inc.’s Amendment No.1 to Annual Report on Form 10-K, filed on May 23, 2014.
(17) Incorporated by reference to Horizon Pharma, Inc.’s Current Report on Form 8-K, filed on June 18, 2014.
(19) Incorporated by reference to Horizon Pharma, Inc.’s Quarterly Report on Form 10-Q, filed on August 7, 2014.
(21) Incorporated by reference to Horizon Pharma Public Limited Company’s Registration Statement on Form S-8, filed on September 22, 2014.
(22) Incorporated by reference to Horizon Pharma Public Limited Company’s Current Report on Form 8-K, filed on October 17, 2014.
Exhibit 10.58

Dated the 4th day of November 2014

JOHN RONAN AND CASTLE COVE PROPERTY DEVELOPMENTS LIMITED

Landlord

HORIZON PHARMA SERVICES LIMITED

Tenant

HORIZON PHARMA PUBLIC LIMITED COMPANY

Guarantor

LEASE

Part First Floor (Rear), Connaught House, 1 Burlington Road, Dublin 4

EVERSHEDS

Solicitors
One Earlsfort Centre
Earlsfort Terrace
Dublin 2

Exhibit 10.58
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
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</thead>
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<td>2    INTERPRETATION</td>
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<td>3    DEMISE</td>
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<td>4    TENANT'S COVENANTS</td>
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</tr>
<tr>
<td>5    LANDLORD'S COVENANTS</td>
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</tr>
<tr>
<td>6    PROVISOS</td>
<td>27</td>
</tr>
<tr>
<td>7    TENANT'S BREAK OPTION</td>
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<td>SCHEDULE 1</td>
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<tr>
<td>SCHEDULE 2</td>
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<tr>
<td>SCHEDULE 3</td>
<td>45</td>
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<td>SCHEDULE 4</td>
<td>48</td>
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<tr>
<td>SCHEDULE 5</td>
<td>49</td>
</tr>
<tr>
<td>SCHEDULE 6</td>
<td>52</td>
</tr>
</tbody>
</table>
THIS LEASE made the 4th day of November 2014

BETWEEN

(1) JOHN RONAN of Dargle Cottage, Dargle, Enniskerry, Co Wicklow AND CASTLE COVE PROPERTY DEVELOPMENTS LIMITED (registration number 406988) having its registered office at c/o Cooney Carey, The Courtyard, Units 15-16 Carmanhall Road, Sandyford, Dublin 18 (the “Landlord” which expression where the context so admits shall include their respective successors in title, administrators and assigns);

(2) HORIZON PHARMA SERVICES LIMITED (registration number 412938) a limited liability company having its registered office at 25/28 North Wall Quay Dublin 1 (the “Tenant” which expression shall where the contract so admits or requires include its successors in title, administrators and permitted assigns); and

(3) HORIZON PHARMA PUBLIC LIMITED COMPANY (registration number 507678) a public limited company having its registered office at 25/28 North Wall Quay Dublin 1 (the “Guarantor” which expression shall where the contract so admits or requires include its successors in title, administrators and permitted assigns)

OPERATIVE PROVISIONS

1 DEFINITIONS:

In this Lease the following expressions shall have the following meanings:

“Arbitration Act”, means the Arbitration Act 2010

“Basement” means the basement of the Building shown on Plans 1 and 2 annexed to this Lease

“Base Rate” the annual rate of interest for the time being chargeable under Section 22 of the Courts Act 1981 or if there is no such rate the nearest corresponding rate

“BER Certificate” A BER certificate as defined by the EPB Regulations

“Block A” means the building shown on Plan 3 annexed to this Lease and thereon outlined in blue

“Break Option Date” the date which is the tenth (10th) anniversary of the Term Commencement Date.

“Building” means the Building described in Part II of the Schedule 1

‘Business Hours’ means the hours of 0700 hrs to 1900 hrs inclusive Monday to Friday excluding bank holidays, or such other business hours as the Landlord (or its agent) acting reasonably may notify to the Tenant in writing (which includes communication by email) from time to time throughout the Term.

“Capital Good” has the meaning attributed to that term under Section 2 and Section 62(2) of the VAT Act.

“Capital Goods Record” has the meaning attributed to that term under Section 64(12) of the VAT Act.

“Car Spaces” means the six (6) car parking spaces more particularly described in paragraph 2 Part IV of Schedule 1.

“Common Areas” means all such areas of the Building as are not for the time being let separately or designed or intended to be let separately and the other facilities which are designed or provided from time to time by the Landlord for common or general use or benefit to the tenants in the Building including without prejudice to the generality of the foregoing the main structure of the Building, the Basement, car park ramp, service yards, roof, foundations, external walls, internal load bearing walls and structural parts of the roof, ceilings and floors, all party structures, office accommodation reserved in the Building for staff employed for the management of the Building, any parts of the Building reserved by the Landlord for the housing of plant, machinery and equipment, bathroom facilities which are not included in any lease of part of the Building, Conduits (except those exclusively serving any Lettable Area) entrance halls, the Gym, the Reception, corridors, passages, lobbies, landings, staircases, the lifts made available for use by the occupiers of the Building and other amenities which are from time to time designated by the Landlord for the common use of the tenants in the Building.

“Conduits” mean all sewers, drains, pipes, gullies, gutters, ducts, mains, watercourses, channels, subways, wires, cables, conduits, flues and other conducting media of whatsoever nature and kind.

‘Connected’ has the meaning set out in Section 97(3) of the VAT Act.
Deed of Renunciation means a valid and effective renunciation of any statutory tenancy renewal rights including any under the provisions of Section 4 of the Landlord and Tenant (Amendment) Act 1994 as amended by Section 47 of the Civil Law (Miscellaneous Provisions) Act 2008.

Easements Rights and Privileges means those specified in Part IV of the Schedule 1.

Enactment means every Act of Parliament and the Oireachtas and Law of the European Community now or hereafter to be passed and every instrument directive regulation and bye-law made thereunder which has force in Ireland.


EURIBOR means:

(a) the percentage rate per annum determined by the Banking Federation of the European Union for the relevant interest period, displayed on the appropriate page of the Telerate screen. If the agreed page is replaced or service ceases to be available, the Landlord may specify another page or service displaying the appropriate rate; or

(b) (if no such rate is available for the relevant period) the arithmetic mean of the rates (rounded up to five decimal places) as supplied to the Landlord at its request, quoted by the reference banks to leading banks in the European interbank market, as of 11:00 a.m. (Brussels time) on the day which is two TARGET Days (ie. days on which the Trans-European Automated Real-time Gross Settlement Express Transfer payment system is open for the settlement of payments in euro) before the first day of the relevant interest period unless market practice differs in the European interbank market, in which case on the day determined by the Landlord in accordance with market practice in the European interbank market (and if quotations would normally be given by leading banks in the European interbank market on more than one day, the Quotation Day will be the last of those days).
“Exceptions and Reservations” means those specified in Part III of Schedule 1

“First Floor Common Areas” Means any Common Areas on the first floor of the Building.

“First Floor Lettable Areas” means all such areas of the first floor of the Building as are for the time being let separately or designed or intended to be let separately and excluding, for the avoidance of doubt, all Common Areas

“First Service Charge” means all costs and expenses which are at any time hereafter during the Term properly expended, incurred or payable by the Landlord or to be expended, incurred or paid in providing all or any of the services set out in Part II of Schedule 2 and discharging the costs specified in Part III of Schedule 2

“Gale Days” means 1st January, 1st April, 1st July and 1st October in every year

“Guarantor” means the person(s) if any named as “Guarantor” at the commencement of this Lease and any person(s) who during the Term covenant(s) with the Landlord in the terms set out in Schedule 5 and references to “Guarantor” include where the context so admits or requires the personal representatives, successors and assigns of any such person(s)

“Group Company” means any company which is a subsidiary or holding company of the Tenant and/or within the same group of companies as the Tenant within the meaning of Section 155 of the Companies Act, 1963

“Gym” means the gym located at Level Basement –1 of the Building comprising 1,216 square feet and shown hatched green on Plan 1 annexed to this Lease

“Gym Rent” means the rent attributable to the Gym calculated at a rate of €25.00 (twenty five euro) per square foot until the 1 August 2015 and, from that date and from each fifth anniversary thereof, at a rate per square foot determined in accordance with Schedule 2, Part I, paragraph 11 on each such review date.

“Insurance Rent” means in respect of any period for which the same is required to be calculated the Tenant’s Proportion of the aggregate of the following costs:

a) The cost properly incurred in insuring the Building against the Insured Risks for the relevant period for the full reinstatement cost of the Building including but not limited to the cost of the following:

   (i) architects, engineers and quantity surveyors and other professional fees and incidental expenses properly incurred (including VAT thereon);

   4
(ii) the costs of shoring up, hoarding, demolishing, site clearing and similar expenses;

(iii) any fees or charges on the submission of an application for planning permission and compliance with Building Regulations and any costs which might be properly incurred in complying with any other Enactment in carrying out all demolition, reinstatement and repair work;

(iv) fire brigade and other emergency services;

(v) a reasonable provision for inflation; and

(vi) all stamp duty and other taxes or duties exigible on any contract or agreement as may be entered into relative to the demolition, reinstatement and repair work;

(b) The reasonable and proper cost of employing the Landlord's Surveyor to determine the reinstatement value of the Building as often as is reasonably necessary but not more than once in any twelve month period.

(c) Any amount which the Landlord may expend in maintaining and effecting insurance in respect of not less than four years loss of rent and First Service Charge and Second Service Charge having regard to potential increases or decreases of rent in accordance with Clause 3 and with any addition to the sum insured as the Landlord may decide in respect of VAT.

(d) Any cost of effecting and maintaining insurance covering the public liability, property owners liability and employers liability in relation to the Premises and anything done therein and insurance in respect of fire brigade charges.
(e) (Without prejudice to all other provisions in this Lease relating to the vitiation of any policy of insurance) any amount which the Landlord may expend in paying all additional premiums and any other amounts on any policy or policies of insurance as a result of anything done or omitted by the Tenant.

(f) Any amount equivalent to the total of all excess sums which the insurers are not liable to pay out on any insurance claim in respect of any of the policies of insurance mentioned in this definition and which the Landlord has expended in replacing the damaged or destroyed parts of the Premises.

(g) Any professional fees relating to insurance including fees for insurance valuations carried out at reasonable intervals and all fees and expenses payable to advisers in connection with effecting and maintaining insurance policies and handling claims required from time to time throughout the Term for reasons of good estate management.

(h) Any amount which the Landlord may expend in effecting and maintaining any other policy or policies of insurance which the Landlord may acting reasonably deem necessary in the interests of good estate management

"Insured Risks" means loss, damage or destruction whether total or partial caused by fire, explosion, lightning, impact, earthquake, aircraft and articles dropped therefrom, flood, storms and tempest, terrorism, riot and civil commotion and malicious damage or bursting or overflowing of water tanks, apparatus and pipes, subsidence and such other risks as the Landlord may from time to time in its reasonable discretion consider prudent or desirable to insure subject to such exclusions and limitations as are from time to time imposed by the insurers

"Landlord’s Specification" means the specification detailed in the document attached at Schedule 4

"Lettable Areas" means all such areas of the Building as are for the time being let separately or designed or intended to be let separately and excluding, for the avoidance of doubt, all Common Areas

"this Lease" means this Lease and any document which is made supplemental to it
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>'Nearby Property'</td>
<td>any land premises or building which adjoins neighbours or is in the vicinity of the Premises including (if applicable) any building or development of which the Premises is part</td>
</tr>
<tr>
<td>'Permitted Use'</td>
<td>means use as offices with associated parking</td>
</tr>
<tr>
<td>'Planning Acts'</td>
<td>means the Planning and Development Acts, 2000 to 2014</td>
</tr>
<tr>
<td>'Plans'</td>
<td>means the plans attached hereto</td>
</tr>
<tr>
<td>'Premises'</td>
<td>means the premises described in Part I of Schedule 1</td>
</tr>
<tr>
<td>'Prescribed Rate'</td>
<td>the rate per cent per day for the time being chargeable under section 1080 of the Taxes Consolidation Act 1997 (or such other periodic rate of interest as may from time to time be chargeable upon arrears of tax) or if the Landlord shall so elect the rate of 10% per annum</td>
</tr>
<tr>
<td>'Quotation Day'</td>
<td>means in relation to any period the day on which quotations for deposits in euro for delivery on the first day of such period would ordinarily be given provided that if for any period quotations would ordinarily be given on more than one date the Quotation Date shall be the last of those days</td>
</tr>
<tr>
<td>'Reception'</td>
<td>means the main reception area comprising 2,195 (two thousand one hundred and ninety five) square feet on the upper ground floor of the Building shown shaded pink on Plan 4 annexed to this Lease and forming part of the Common Areas</td>
</tr>
<tr>
<td>'Reception Rent'</td>
<td>means the rent attributable to the Reception calculated at a rate of €50.00 (fifty euro) per square foot until 1 August 2015 and, from that date and from every fifth anniversary thereof, at a rate per square foot determined in accordance with the Schedule 2, Part I, paragraph 11 on each such review date.</td>
</tr>
<tr>
<td>'Rent Commencement Date'</td>
<td>means day of 2014</td>
</tr>
<tr>
<td>'Safety File'</td>
<td>means the file to be maintained pursuant to the Safety Health and Welfare at Work (Construction) Regulations 2006 to 2013</td>
</tr>
<tr>
<td>'Second Service Charge'</td>
<td>Means all costs and expenses which are at any time during the Term properly expended, incurred or payable by the Landlord or to be expended, incurred or paid in providing all or any of the services set out in Part II of Schedule 6 and discharging the costs specified in Part III of Schedule 6.</td>
</tr>
</tbody>
</table>
“Tenant’s Proportion” means the proportion which the net lettable floor area of the Premises (which is agreed as being 10,266 square feet (ten thousand two hundred and sixty six square feet)) bears to the net lettable floor area of all lettable areas of the Building and calculated in accordance with the Measurement Practice and Guidance Notes issued by the Irish Auctioneers and Valuers Institute and the Society of Chartered Surveyors in the Republic of Ireland.

“Tenant’s Share” means the proportion which the net lettable floor area of the Premises (which is agreed as being 10,266 square feet (ten thousand two hundred and sixty six square feet)) bears to the net lettable floor area of all First Floor Lettable Areas and calculated in accordance with the Measurement Practice and Guidance Notes issued by the Irish Auctioneers and Valuers Institute and the Society of Chartered Surveyors in the Republic of Ireland.

“Term” means the term of fifteen (15) years commencing on (and including) the Term Commencement Date and expiring on the day of

“Term Commencement Date” means the day of                      2014

“Utilities” means water, drainage, gas, electricity, soils and waste of all kinds, telephone and other communication systems, and any other services.

“VAT” means Value Added Tax or any tax of a similar nature that may be substituted for it.

“VAT Act” means the Value Added Tax Consolidation Act 2010 as amended, re-enacted or extended from time to time.

2 INTERPRETATION

In this Lease:

(a) Unless the context otherwise requires words importing the singular include the plural and vice versa and words importing one gender include both other genders; any references to a schedule is to a schedule to this Lease; and references to clauses or sub-clauses are to clauses or sub-clauses of this Lease.

(b) References to a month or months are to a calendar month or months.

(c) Where a party comprises more than one person covenants and obligations of that party take effect as joint and several covenants and obligations.
Any right of (or covenant to permit) the Landlord to enter on the Premises shall also be construed as entitling the Landlord to remain on the Premises with or without equipment and permitting such right to be exercised by all persons properly authorised by the Landlord.

The last year of the Term includes the final year of the Term if it shall determine otherwise then by effluxion of time and references to the expiry of the Term include such other determination.

Reference to any statute or statutes (whether specifically named or not) or to any sections or sub-sections therein shall include any amendments or re-enactments thereof from time to time in force and all statutory instruments, orders, notices, regulations, directions, bye-laws, permissions and plans from time to time made issued or given thereunder or deriving validity therefrom.

The titles or headings appearing in this Lease are for reference only and shall not affect its construction or interpretation.

3 DEMISE

In consideration of the rents reserved by this Lease and of the covenants on the part of the Tenant contained in this Lease the Landlord demises unto the Tenant ALL THAT the Premises together with the Easements Rights and Privileges but excepting and reserving unto the Landlord the Exceptions and Reservations TO HOLD the Premises unto the Tenant for the Term YIELDING AND PAYING therefor during the Term:

3.1 FIRSTLY the initial yearly rent of €482,970.00 (four hundred and eighty two thousand, nine hundred and seventy euro) per annum being €461,970.00 (four hundred and sixty one thousand nine hundred and seventy euro) per annum in respect of the office premises and €21,000.00 (twenty one thousand euro) per annum in respect of the Car Spaces (subject to review in accordance with Schedule 3) to be paid as and from the Rent Commencement Date by four equal quarterly payments in advance on the Gale Days the first payment to be made on the date of this Lease;

3.2 SECONDLy by way of additional rent the Tenant’s Proportion of the First Service Charge payable at the times and in the manner set out in Schedule 2;

3.3 THIRDLY by way of additional rent the Insurance Rent from time to time payable within fourteen (14) days of demand

3.4 AND FOURTHLY by way of additional rent the Tenant’ s Share of the Second Service Charge payable at the times and in the manner set out in Schedule 6;

in each case to be paid (at the option of the Landlord exercisable on any number of occasions) either by standing order, credit transfer, direct debit mandate or cheque.

4 TENANT’S COVENANTS

The Tenant hereby covenants with the Landlord throughout the Term:

4.1 Pay Rent, First Service Charge, Second Service Charge and Insurance Rent

To pay the rents and the reviewed rents hereby reserved on the days and in manner aforesaid without deduction counterclaim or set-off.

4.2 Pay Value Added Tax
4.2.1 To pay (on receipt of proper VAT invoices) and keep the Landlord indemnified against all VAT which may from time to time be properly charged on the rents and / or any other monies payable under this Lease.

4.2.2 The Landlord has exercised its option to tax (the “Landlord’s Option to Tax”) the rents payable under this Lease pursuant to Section 97 of the VAT Act. The Tenant shall pay to the Landlord any VAT properly chargeable on the rents and any other payments reserved or payable pursuant to this Lease subject to receipt of a proper VAT invoice.

4.2.3 At any time during the Term the Landlord may terminate the Landlord’s Option to Tax in respect of this Lease and shall notify each termination forthwith to the Tenant.

4.2.4 Where at any time during the Term the Landlord has terminated the Landlord’s Option to Tax, the Landlord may thereafter from time to time during the Term exercise the Landlord’s Option to Tax the rents payable under this Lease by giving notice to the Tenant pursuant to Section 97(1)(c)(ii) and where such notice is given the Tenant shall thereafter pay to the Landlord (on receipt of proper VAT invoices), all VAT on the rents properly payable under this Lease.

4.2.5 Where, during the Term, a situation arises where the Landlord from time to time and the Tenant from time to time become connected persons within the meaning of VAT Act and the Tenant has less than 90% VAT recovery such that the Landlord suffers a deductibility adjustment under VAT Act, then the Tenant will reimburse, and indemnify the Landlord on a net of tax basis, the amount of the deductibility adjustment. In the event of a later refund or credit to the Landlord from the Revenue Commissioners of any sum or part thereof paid by the Tenant pursuant to this clause or clause 4.18.9 the Landlord shall pay such sum or part thereof as appropriate so received to the Tenant within 14 days of receipt. For the purposes of this clause 4.2.5 “Tenant” shall mean the party who has made the actual payment to the Landlord pursuant to this clause or to clause 4.18.9 and not (unless paid by same) any successor in title to the Tenant. The Landlord further acknowledges and agrees that where the Landlord’s Option to Tax is terminated the Landlord shall during the term of this lease avail in so far as it is able of the next opportunity to re-exercise the Landlord’s Option to tax and shall use reasonable endeavours to procure that any claim for a credit or refund of VAT due to the Landlord as a result of such re-exercise is processed expeditiously.

4.2.6 Notwithstanding any other provision of this Lease, the Landlord agrees that strictly subject to the Tenant providing it with a valid authorisation under Section 56(3) of the VAT Act, it shall (i) apply the zero rate of VAT to the rents and to any other payments reserved or payable by the Tenant pursuant to this Lease; and (ii) provide the Tenant with a valid VAT invoice in accordance with Chapter 2, Part 9 of the VAT Act in respect of any taxable supplies made by it to the Tenant. If the Landlord charges VAT incorrectly in respect of any taxable supplies made by it to the Tenant, the Landlord and the Tenant agree that they will, in a timely manner, take such action as may be necessary to ensure that a correct invoice is issued. However, in the event that the Landlord has not been furnished with an authorisation under Section 56(3) of the VAT Act as aforesaid at any time, it shall be entitled to apply the full rate of VAT applicable to the said rents or other payments.

4.2.7 The landlord covenants that it is at the date of the execution of this Lease, and shall continue to be, an accountable person for the purposes of Part 2, of the VAT Act.
4.2.8 In the event of an agreed surrender of this Lease for any reason (excluding by way of forfeiture or ejectment), and if at the date of such agreed surrender (if any) either the Tenant or one of its predecessors in title has created a Capital Good in respect of the Premises the Landlord shall agree at that time to co-operate with the Tenant and may if, reasonable, enter into an agreement in writing to become responsible for any such Capital Good from the date of the surrender of this lease in accordance with Section 64(7) of the VAT Act and if applicable the Tenant shall issue to the Landlord a copy of the Tenant’s Capital Goods Record in accordance with Section 64(7) of the VAT Act PROVIDED ALWAYS that the Landlord shall not be required to enter into such an agreement in circumstances where becoming responsible for the refurbishment Capital Good would cause an irrecoverable VAT cost for the Landlord (either as a VAT clawback or a VAT payment obligation).

4.3 Interest on late payments

Without prejudice to any other right or remedy or power contained in this Lease otherwise available to the Landlord, in the event that any of the rents hereinbefore reserved (whether formally demanded or not) or any other sums payable by the Tenant to the Landlord under this Lease are not received by the Landlord within fourteen (14) days after the due date for payment, to pay interest on such rent or sum at the Prescribed Rate calculated for the period commencing on the due date for payment and ending on the date the rent or sum is received by the Landlord (both before and after any judgement).

4.4 Pay Rates and Outgoings

4.4.1 To pay and discharge all rates water rates taxes duties charges assessments impositions burdens and outgoings of an annual or recurring nature and also of a non-annual or non-recurring nature where the same are legally chargeable against the Tenant or occupier and whether Parliamentary or Local or of any other description that may be assessed charged or imposed upon the Premises or the owner or occupier in respect thereof during the Term (excluding any tax payable by the Landlord upon any of the rent herein received or occasioned by any disposition of or dealing with the reversion of this lease or any capital or income taxes payable by the Landlord) and to refund to the Landlord any such amounts paid by it in respect of the Premises PROVIDED THAT no VAT shall be payable by the Tenant to the Landlord solely under this clause 4.4.1 but, for the avoidance of doubt, this proviso shall not affect the Tenant’s liability to pay VAT in accordance with clauses 4.2, 4.18 or any other provision in this lease.

4.4.2 To be solely responsible for and promptly pay all charges for water gas electricity or heat (if any) or any other utility used or consumed in the Premises during the Term but so that the Landlord shall not be liable in any event for any interruption or failure in the supply of any such utilities to the Premises.

4.5 Comply with Enactments

At its own expense to observe and comply with all Enactments and to do and execute all such works as are or shall be at any time during the Term under or by virtue of all Enactments and by any local or other authority directed or required to be done or executed in respect of the Premises or any part thereof whether by the owner or occupier thereof and to indemnify and keep the Landlord indemnified against all or any claims demands and liability in respect thereof.

4.6 Alterations

4.6.1 Not to erect or to permit or suffer to be erected any new building upon the Premises or to make or to permit or suffer to be made any external or structural alteration in or addition whatsoever to the Premises;
4.6.2 (Without prejudice to Clause 4.6.1) not without the previous consent in writing of the Landlord (such consent not to be unreasonably withheld or delayed) to make any other alterations or additions to the Premises or any alterations or additions to any Landlord’s fixtures, fittings or equipment or the Conduits.

4.6.3 (Without prejudice to Clause 4.6.1) not without the previous consent in writing of the Landlord (not to be unreasonably withheld or delayed) to erect any partitioning or carry out any other internal non-structural alteration within the Premises and any such erection or alteration for which consent is granted shall be carried out in accordance with plans and specifications to be first approved by and to the reasonable satisfaction in all respects of the Landlord’s Architects or Surveyors and the Tenant shall pay the reasonable charges for such Architects or Surveyors and of the Landlord’s Solicitors incurred for each such consent.

4.6.4 To furnish to the Landlord on completion of any permitted alterations certificates of compliance with or exemption from all relevant planning and building control legislation from competent and suitably professionally qualified persons acceptable in accordance with prudent conveyancing standards such certificates to be in the form then currently approved by the Law Society of Ireland.

4.6.5 It shall be reasonable for the Landlord to impose as a condition of any consent granted pursuant to this Clause 4.6 that the Tenant shall reinstate the Premises at the expiration or sooner determination of the Term to its condition prior to any alterations being carried out or if so required by the Landlord in accordance with the Landlord’s Specification.

4.6.6 Without prejudice to the generality of Clause 4.5:

(a) if the original of the Safety File for the Premises is provided to the Tenant on the request of the Tenant, to maintain and keep safe the Safety File and to amend and update the Safety File when necessary in respect of any alterations carried out by the Tenant from time to time, and to furnish the original Safety File to the Landlord upon request if required by the Landlord in connection with a dealing relating to the Landlord’s interest in the Premises; or

(b) in the event that the Safety File for the Premises is retained elsewhere or forms part of the Safety File for the Building, to provide to the Landlord within thirty (30) days of any such alterations all information and documentation required to allow the Landlord to amend and update the Safety File when necessary in respect of any alterations carried out by the Tenant from time to time.

4.6.7 The Landlord may as a condition to giving any consent under any of the sub-clauses in this clause 4.6 or where the provisions of this clause 4.6 are deemed to apply require the Tenant to enter into such covenants and licences, to provide and maintain such insurances and to comply with such requirements as the Landlord shall reasonably require in relation to the execution of any works, their repair and maintenance and their removal and the reinstatement of the Premises on termination of the Term or otherwise and any consent under or by virtue of any of the sub-clauses in this clause 4.6 shall be subject to the Tenant complying with the Planning Acts (including Building Regulations) and any other applicable Act.

4.7 Not To Avoid Insurance

4.7.1 Not to knowingly do or permit or suffer upon or bring or suffer to be brought on to the Premises any matter or thing or article which shall or may cause the policy or policies for the insurance of the Premises or of any adjoining or neighbouring premises or any part thereof to become void or voidable or the premium or
4.7.2 In the event of the Premises, or any other premises in the Building or any part thereof being destroyed or damaged from or by any of the Insured Risks and the whole or part of the insurance money in respect of the same being irrevocably by reason solely or in part then and in every such case the Tenant shall forthwith pay to the Landlord the whole or (as the case may require) a fair proportion of the cost of rebuilding and reinstating the Premises and any other premises in the Building in respect of which the Landlord’s insurance shall be vitiated by the act, neglect or default of the Tenant.

4.8 Repair Maintain and Keep Tidy

4.8.1 To repair, maintain, renew and keep in good and substantial repair and condition the Premises and, as often as may be necessary, to reinstate or renew any part or parts of the Premises and as and when necessary, to replace any Landlord’s fixtures and fittings in the Premises which become beyond repair, excluding damage by any Insured Risk (unless the insurance money shall have been rendered irrecoverable or insufficient in whole or in part due to the act, neglect or default of the Tenant or of any person deriving title under or through it or their respective servants, agents or invitees).

4.8.2 To keep the Premises clean and tidy and free from deposits of material or refuse and not to bring or keep or suffer to be brought or kept on the Premises or any part of any of them any dump or rubbish or scrap heap or anything which in the opinion of the Landlord is or may become unclean, unsightly, noisome or offensive or liable to detract from the quality, amenity or reputation of the Building or any adjoining premises of the Building as a high quality office and so often as it shall be necessary or desirable to remove from the Premises all such refuse rubbish and scrap which may accumulate or be there.

4.9 Decoration

Without prejudice to the generality of the clauses 4.8.1 and 4.8.2 above to paint with two coats at least of good quality paint all the interior of the Premises as are usually painted in a good and workmanlike manner such painting of the inside parts to be carried out not less than once in every fifth year of the Term the last such painting to be in the year immediately preceding the termination of this Lease and at the same time with every said inside painting to paper grain and varnish and colour such parts of the inside of the Premises as are usually or have been previously papered grained varnished or coloured.

4.10 Permit Inspection

4.10.1 To permit the Landlord and its agents and workmen with all necessary appliances to enter upon the Premises at all reasonable times after giving not less than 24 hours prior written notice (save in the case of emergency when no notice shall be required) to the Tenant for the purpose of viewing the condition thereof taking a schedule of the fixtures and fittings therein inspecting any works in progress or of exercising any of the rights described in Part III of Schedule 1 and upon written notice given by the Landlord to execute any repairs lawfully required by such notice for which the Tenant is liable under the provisions hereof and if the Tenant shall not execute such repairs within 21 days of the date of the service upon it of such notice (or if there is any emergency then within such lesser period as may be reasonably practicable but in such event without any delay whatsoever) the Landlord may itself execute such
repairs and the costs incurred by it in so doing shall be paid by the Tenant to the Landlord upon demand and shall be a debt recoverable from the Tenant by the Landlord in any court of competent jurisdiction;

4.10.2 To pay to the Landlord on demand all fees and expenses vouched and properly incurred by the Landlord and / or its servants and agents in connection with the preparation of any notice pursuant to this sub-clause whether during or after the expiration or sooner determination of the Term.

4.11 Permit Landlord’s Works

4.11.1 To permit the Landlord and all persons authorised by it and their officers employees agents contractors licensees and workmen at all reasonable times after reasonable prior notice (except in case of emergency when no notice shall be required) to enter (and if necessary to erect and maintain equipment and scaffolding) upon the Premises with all necessary appliances:

(a) to execute repairs, alterations, painting, redecoration or other work to the Premises or any other part of the Building; and

(b) for the purpose of inspecting, repairing, renewing, cleansing, emptying, maintaining or protecting any Conduits in under or over the Premises in connection with or for the accommodation of any adjoining or neighbouring premises.

in either case the person or persons exercising such rights making good or paying compensation for any damage (other than consequential loss or damage) thereby occasioned to the Premises or any Tenant’s fixtures and fittings.

4.12 Nuisance

Not to carry on or permit or suffer to be carried on upon any part of the Premises any offensive or noisy trade business manufacture or occupation or permit or suffer the Premises to be used for any illegal purposes nor to do or permit or suffer to be done in or upon the Premises anything which in the opinion of the Landlord may be a nuisance annoyance or disturbance or to cause damage or interference to the beneficial occupation of the occupants of the Building and to diligently and expeditiously execute all such works as soon as possible as may be necessary for abating any such nuisance in obedience to a notice lawfully served by a local or public authority or pursuant to any court order or in obedience to any notice properly served by the Landlord pursuant to this Clause 4.12 and in default thereof to pay to the Landlord all reasonable and properly vouched costs charges and expenses which may be incurred by the Landlord in abating such nuisance in respect of the Premises.

4.13 Prevent Encroachment

To use all reasonable endeavours to prevent any easement or right belonging to or used with the Premises from being obstructed or lost and not to allow any encroachment to be made or easements to be acquired on under or over the Premises and to give notice to the Landlord forthwith of any encroachment which might have that effect and to join in at the cost of the Landlord with any objection or proceedings which the Landlord may take in respect of such encroachment.

4.14 Signs

4.14.1 Not to paint fix or exhibit or permit or suffer to be painted fixed or exhibited so as to be visible from outside the Premises any advertisement notice sign placard hoarding name or writing to or upon any part of the exterior of the Premises or on or in the windows or external walls of the Premises or upon any entrance doors thereof, save
that the Tenant may, with the prior consent in writing of the Landlord (not to be unreasonably withheld), display and maintain in the lift lobby on the first floor of the Building immediately outside the Premises, and on the board in the Reception maintained for that purpose and any other tenant directories maintained by the Landlord in the Building or the curtilage thereof, a name-plate or sign showing the usual trade name of every permitted occupier of the Premises and may install signage identifying the Tenant’s car spaces in the Basement PROVIDED ALWAYS that in connection with any such consent which may be given as aforesaid any necessary consent of the appropriate authorities under any planning or other legislation be also first obtained by the Tenant.

4.14.2 Not to hang or place or exhibit or permit or suffer to be hung or placed or exhibited any goods outside the Premises or the entrance doors or display windows of the Premises.

4.14.3 Not to install any blinds or curtains in the windows of the Premises or to substitute such blinds or curtains from time to time without first obtaining the prior written consent of the Landlord.

4.15 Aerials

Not without the prior written consent of the Landlord (not to be unreasonably withheld) to erect or permit the erection of any television or radio or telecommunication receiving aerials or antennae or other apparatus on the exterior of the Premises.

4.16 Reletting Signs and Viewing

4.16.1 To permit the Landlord during the six months immediately preceding the expiration of the Term to affix and retain without interference to or upon any part of the Premises (but so as not unduly to obscure the windows thereof or interfere with the Tenant’s use thereof) a notice for reletting the same and during the said six months to permit persons with written authority from the Landlord or its agents at reasonable times of the day (upon reasonable prior written notice) to view the Premises;

4.16.2 To permit upon reasonable prior written notice at all reasonable times during the Term hereof prospective purchasers of or dealers in or agents instructed in connection with the sale of the Landlord’s reversion or of any interest superior to the Term to view the Premises without interruption provided the same are authorised in writing by the Landlord or its agent.

4.17 Cost of notices and consents

To give immediate notice thereof to the Landlord of any notice or claim affecting the Premises and to pay all costs charges and expenses (including Solicitors’ costs and surveyors’ fees) vouched and properly incurred by the Landlord:

4.17.1 for the purpose of or incidental to or in contemplation of the preparation and service of a notice under Section 14 of the Conveyancing and Law of Property Act 1881 requiring the Tenant to remedy a breach of any of the covenants herein contained notwithstanding forfeiture for such breach shall be avoided otherwise than by relief granted by the Courts;

4.17.2 in connection with the enforcement (whether during or after the expiry of the Term) of the Tenant’s obligations under this Lease including the preparation and service of all notices and schedules of dilapidations;

4.17.3 in respect of each application for consent licence or approval under this Lease whether or not the application is withdrawn or rejected.
4.18 Alienation

4.18.1 Not to assign underlet or part with or share the possession control or occupation of the whole or any part of the Premises save in accordance with this clause 4.18;

4.18.2 Not to assign underlet or part with or share the possession control or occupation of the whole or any part of the Premises without the consent in writing of the Landlord first obtained such consent not to be unreasonably withheld or delayed to a respectable and responsible assignee or underlessee of good and sufficient financial standing (taking into account the financial obligations under this Lease or an appropriate proportion of such financial obligations in the case of an underlease of part only) and equal or greater financial standing to the existing tenant proof of which is furnished to the Landlord and upon any such assignment to obtain if the Landlord shall so require an acceptable guarantor or guarantors who shall if required by the Landlord enter into a direct covenant in the same form (mutatis mutandis) as that contained in Schedule 5 for any assignee and subject to the following provisions or such of them as may be appropriate, that is to say:

4.18.3 The Tenant shall prior to any such assignment or underlease apply to the Landlord and give all information concerning the proposed assignee or underlessee as the Landlord may reasonably require.

4.18.4 The Landlord’s consent to any such assignment or underletting shall be given in writing and the Tenant shall pay the Landlord’s reasonable costs in connection with the application for such consent whether or not such consent is granted or refused.

4.18.5 In the case of an assignment shall be of the entire of the Premises.

4.18.6 In the case of an underlease

(a) the same shall be of the entire of the Premises or part of the Premises provided however that there shall be no more than two occupiers (including if still in occupation the Tenant) of the Premises at any one time and no such underlessee shall be permitted to underlet part of the underlet premises;

(b) the sub-tenant shall pay an amount equal to the higher of (i) the then open market rack rental value for the Premises with the benefit of the Easements Rights and Privileges at the time of the granting of such underlease (or the appropriate part thereof in the case of an underlease of part only) and (ii) the yearly rent payable under this Lease at the time of the granting of such underlease (or the appropriate part thereof in the case of an underlease of part only);

(c) the Tenant shall procure that the sub-lessee shall execute in advance of such sub-letting, whether of all or of part only of the Premises, a Deed of Renunciation in respect of any statutory rights of renewal which might accrue to it on the expiration of such sub-lease and shall indemnify the Landlord against any loss, cost, claim, expense, action or demand arising in respect of any breach of that obligation or as a result of any such statutory rights of renewal nevertheless accruing to such sub tenant;

(d) unless the Landlord otherwise elects, the amount of rent charged under any such underlease(s) and any other evidence in relation to any such underlease(s) shall be disregarded in any review of the Rent payable under this Lease pursuant to Schedule 3
4.18.7 An underlessee shall if required by the Landlord enter into a direct covenant with the Landlord to perform and observe all the covenants (other than that for payment of the rent hereby reserved) and conditions contained in this Lease (or insofar as they relate to or affect the premises underlet in the case of an underlease of part only) and every such underlease shall also be subject to the following conditions, that is to say that it shall contain:

(i) an unqualified covenant on the part of the underlessee not to assign underlet or part with or share the possession of part only of the premises thereby demised;

(ii) a covenant on the part of the underlessee not to assign or underlet the premises thereby demised without obtaining the previous consent in writing of the Landlord hereto not to be unreasonably withheld or delayed;

(iii) covenants and conditions in the same terms as nearly as circumstances admit as those contained in this Lease;

(iv) a covenant, condition or proviso under which the rent reserved by the underlease shall be reviewed at the Review Date (as defined in Schedule 3 of this Lease)

(v) a covenant, condition or proviso under which the rent from time to time payable under such underlease shall not be less than the rent from time to time payable hereunder; and

(vi) a covenant that any underleases granted out of such underlease whether immediately or mediately shall contain provisions similar to those in this clause 4.18.7.

4.18.8 It shall be reasonable for the Landlord to withhold consent to any proposed assignment, parting with or sharing of possession or control or occupation of the Premises if such assignment or sublet, etc, would result in the termination of the Landlord's Option to Tax under Section 97(1) of the VAT Act.

4.18.9 The Tenant shall indemnify and keep the Landlord indemnified from and against all losses, costs, claims, demands, proceedings, damages, expenses and liabilities arising out of the termination of the Landlord's Option to Tax under Section 97(1)(d)(iii),(iv) and (v) of the VAT Act to the extent that on any such termination the Tenant shall, without prejudice to the generality of the foregoing, pay on demand to the Landlord:

(i) an amount equal to the amount payable by the Landlord to the Revenue Commissioners under the VAT Act as a result of the termination of the Landlord's Option to Tax referred to in this clause; and

(ii) where the amount payable under sub-paragraph (i) above is or will be subject to tax in the hands of the Landlord such further sum as will leave the Landlord in the same financial position as if such amount had not been subject to tax;

(iii) In respect of the above, the Landlord agrees to furnish to the Tenant a calculation of any sums due (the "Statement") signed by the Landlord's auditors or tax advisors and such Statement shall (save in the case of manifest error) be final and binding on the parties.
4.18.10 In the case of any permitted underlease the Tenant further covenants and agrees:

(a) to enforce at the Tenant’s own expense the performance and observance by every such undertenant of the covenants provisions and conditions of the underlease and not at any time (either expressly or by implication) to waive any breach of the same;

(b) not to agree any adjustment or revision to the rent with the undertenant without the prior written consent of the Landlord;

(c) not to vary the terms of any permitted underlease without the prior written consent of the Landlord; and

(d) to ensure that vacant possession of the underlet premises is quietly yielded up by the undertenant at the expiration or sooner determination of the permitted term of the underlease (and in any event on Termination of the Term) free from any claims or potential claims under the Landlord and Tenant Acts 1967 to 2010.

4.18.11 In clause 4.18.7 and in clause 4.18.10 the expression “underlease” shall include an underletting as well (in an appropriate case) as a sufferance of any person to occupy the Premises or any part of it as licensee or as concessionaire and the expression “undertenant” and “underlet premises” shall be construed accordingly.

4.18.12 PROVIDED ALWAYS and it is expressly agreed and declared that without prejudice to any other ground on which the Landlord may be entitled to withhold or refuse its consent the Landlord shall be entitled and it shall be deemed reasonable for the Landlord to refuse its consent to any alienation if:

(a) the proposed assignee undertenant or other person as aforesaid intends to alter the user of the Premises or any part of it in a manner which would be prohibited under the provisions of this Lease relating to permitted user of the Premises or under any superior lease or other deed or document affecting the Premises or the Landlords title;

(b) in the Landlord’s reasonable opinion there are at the date of the application for consent any material outstanding breaches of any of the covenants on the part of the Tenant or conditions contained in this Lease;

(c) in the Landlord’s reasonable opinion the alienation is to a person Connected to the Landlord; or

(d) where the proposed assignee or undertenant or other person as aforesaid enjoys diplomatic or state immunity.

4.18.13 To furnish to the Landlord or the assignee or undertenant as appropriate a capital good record in accordance with the provisions of Section 95 (9) or Section 64 (7) of the VAT Act at or prior to any permitted assignment or underlease.

4.18.14 If at any time during the Term the provisions of Section 32(2) of the Local Government Reform Act 2014 apply to the Premises or any part of it to give to the rating authority the notice provided for in sub-section 32(2)(a) of that Act within the period specified in that sub-section (with a copy to the Landlord at the same time) and to comply with the provisions of Section 32 of the said Act.
4.18.15 It shall be reasonable for the Landlord to require as a pre-condition to its consent that the assignee undertenant licensee concessionaire or other person executes and delivers to the Landlord prior to or contemporaneously with the alienation in question a Deed of Renunciation such that the Landlord is satisfied that on the determination of the Term whether by effluxion of time re-entry notice surrender (whether by operation of law or otherwise) or by any other means whatsoever of the Term (or if sooner the determination of the term of any underlease) there will be no right or entitlement to a new tenancy under Part 2 of the Landlord and Tenant (Amendment) act 1980 as amended.

4.18.16 Without prejudice to the indemnity provided for in clause 4.18.9, prior to any assignment, underlease, parting with or sharing of possession or control or occupation of the whole Premises (hereinafter referred to as an `Alienation`), the Tenant shall notify the Landlord in writing prior to such Alienation in accordance with clause 14.8.3 indicating the name, address and other relevant details as regards the proposed assignee, occupant or under-lessee in order that the Landlord can establish and confirm in writing to the Tenant whether the proposed assignee, occupant or under-lessee is or is not connected with the Landlord within the meaning of Section 97(3) of the VAT Act AND in the event of the proposed assignee, occupant or under-lessee being so connected whether the Alienation would result in a termination of the Landlord’s option to tax the Lease pursuant to Section 97 (1)(d)(iii)(iv) or (v) of the VAT Act. In the event that the proposed Alienation would result in a termination of the Landlord’s option to tax pursuant to Section 97 (1)(d)(iii)(iv) or (v) of the VAT Act and the Tenant still wishes to proceed with the Alienation and the Landlord consents to such Alienation and the Tenant otherwise complies with the covenants and conditions of this clause 4.18 and this Lease in respect of such Alienation), the Tenant shall prior to such Alienation pay to the Landlord a reimbursement amount in respect of any VAT clawback or VAT payment obligation which would be suffered by the Landlord as a result of the termination of the Landlord’s option to tax. If this reimbursement amount is subject to Tax in the hands of the Landlord, the Tenant shall also pay, in addition to the reimbursement amount, such further sum which will leave the Landlord in the same position as if such amount had not been subject to Tax. The Landlord shall furnish to the Tenant a calculation of the sums due under this clause 14.8.16 (the “VAT Statement”) signed by the auditors or tax advisers pursuant to Clause 14.8.9 above which VAT Statement shall, save in the case of manifest error, be final and binding on the parties.

4.19 Notice of Alienation

Within one calendar month after the execution of any assignment transfer underlease or the devolution of the Premises to give notice in writing with particulars to the Landlord’s Solicitors and to produce to them with such notice such assignment or transfer or the counterpart of such underlease or the probate or letters of administration or other instrument under which such devolution arises.

4.20 Disclosure of Notices

Upon receipt of any notice order requisition direction or other thing from a competent authority affecting or likely to affect the Premises (whether the same shall be served directly on the Tenant or the original or a copy thereof be received by the Tenant from any person whatsoever) forthwith to deliver to the Landlord a copy thereof and so far as the provisions hereof require the Tenant so to do to comply therewith at its own expense.

4.21 Unauthorised User

4.21.1 Not to use or occupy the Premises or any part thereof or permit the same to be used or occupied for any other purpose than the Permitted Use.
4.21.2 Not to permit or suffer anyone to sleep in the Premises and not to use or permit or suffer the use of the same or any part thereof for residential purposes or as licensed premises for the sale of excisable or intoxicating liquors or as an amusement arcade or bingo hall or any similar user.

4.21.3 Not to use the Premises or any part thereof or permit or suffer the same to be used for gaming or as a betting office.

4.21.4 Not to have or permit any sale by auction in or upon the Premises or any part thereof.

4.22 Machinery Overloading and Inflammable Goods

4.22.1 Not (except so far as the same shall be ancillary to the Permitted Use and the installation or use of the same shall not amount to a breach of any other provision herein) to erect or install or use in or upon any part of the Premises any steam gas electric or other engine or machinery of any kind.

4.22.2 Not to do or permit or bring in or upon the Premises anything which may throw on the Premises or any adjoining premises any weight or strain in excess of that which such premises are capable of bearing with due margin for safety and in particular not to overload the floors or the electrical installations or the other services of in or to the Premises nor suspend any excessive weight from the ceilings or walls, stanchions or the structure thereof. The Tenant shall seek professional advice at the Tenants own expense to ensure that there shall not be an infringement of this covenant.

4.22.3 Not to have store or keep upon the Premises or any part thereof any substance of an explosive or of an inflammable or dangerous nature or such as might increase the risk of fire or explosion or which might attack or in any way injure by percolation corrosion or otherwise the Premises or any adjoining premises or the keeping or use whereof may contravene any statutory or local regulation or bye-law and in particular without prejudice to the generality of the foregoing not to keep portable gas appliances for use on the Premises.

4.23 Planning Acts

4.23.1 Not to do or omit or permit to be done or omitted anything on or in connection with the Premises the doing or omission of which shall be a contravention of the Planning Acts and / or the Building Regulations, or of any notices, orders, licences, consents, permissions and conditions (if any) served, made, granted or imposed thereunder or under any enactment repealed thereby and to indemnify (as well after the expiration of the Term by effluxion of time or otherwise as during its continuance) and keep indemnified the Landlord against all actions, proceedings, damages, penalties, costs, charges, claims and demands in respect of such acts and omissions or any of them and against the costs of any application for Planning Permissions obtained by the Tenant and the works and things done in pursuance thereof.

4.23.2 In the event of the Landlord giving written consent to any of the matters in respect of which the Landlord’s consent shall be required under the provisions of this Lease or otherwise and in the event of permission from any Planning Authority under the Planning Acts and / or the Building Regulations being necessary for any additions, alterations, or changes in or to the Premises or for the change of user thereof or for any development for which such consent has been sought and obtained to apply at the cost of the Tenant to the relevant local authority for all consents and permissions which may be required in connection therewith and to give notice to the Landlord of the granting or refusal (as the case may be) of all such approvals, certificates, consents and permissions forthwith on the receipt thereof and to comply with all conditions, regulations, bye-laws and other matters prescribed by any competent
authority either generally or specifically in respect thereof and to carry out such works at the Tenant’s own expense in a
good and workmanlike manner to the reasonable satisfaction of the Landlord and without prejudice to the generality of the
foregoing or to any other obligation of the Tenant or any other requirement of the Landlord promptly furnish to the Landlord:

(a) a copy of any commencement notice or 7 day notice (including if reasonably required by the Landlord all plans,
documents, calculations, specifications, particulars, certificates and notices accompanying it) filed with or given to the
building control or other competent authority in accordance with the Building Regulations;

(b) any application for a fire safety certificate and/or disability access certificate (or other certificate under the Building
Regulations) for its prior approval (which approval shall not, subject to the provisions of clause 4.6 be unreasonably
withheld or delayed);

(c) any fire safety certificate and disability access certificate (or other certificate under the Building Regulations) issued;

(d) within one month of the practical completion of the works a certificate of opinion of compliance by a member of the
Royal Institute of Architects in Ireland or Engineers Ireland (or any successor or substituted body of either) that the
design and construction of the works or (as applicable) the change of use comply with the Planning Acts (including
Building Regulations) and that all such works and/or change of use have been carried out in substantial compliance with
the plans lodged with the relevant applications for planning permission, a fire safety certificate and/or disability access certificate as amended by any conditions imposed by the planning authority or building control or other
competent authority; and

(e) a certified copy of the Certificate of Compliance on Completion (including if reasonably required by the Landlord, all
plans, documents and other evidence accompanying it) submitted to the building control or other competent authority in accordance with the Building Regulations together with evidence that the particulars relating to such Certificate have been entered by the building control or other competent authority on the relevant register maintained under the Building Regulations.

4.23.3 To give notice forthwith to the Landlord of any notice order or proposal for a notice or order served on the Tenant under the
Planning Acts and / or the Building Regulations and if so required by the Landlord to produce the same and at the request
the Landlord and the cost of the Tenant to make or join in making such objections or representations in respect of any
proposals as the Landlord may require.

4.23.4 To comply at its own cost with any notices or orders served on the Tenant in respect of matters for which the Tenant its
servants or agents are responsible hereunder and to comply with all conditions attached to any permission granted under the
provisions of the Planning Acts and / or the Building Regulations.

4.23.5 Not to implement any planning permission before it and any necessary fire safety certificates have been produced to and
approved by the Landlord (such approval not to be unreasonably withheld or delayed).

4.23.6 If and when called upon to do so to produce to the Landlord or its surveyors all such plans, documents and other evidence
as the Landlord may reasonably require in order to satisfy itself that the provisions of this clause 4.23 have been complied
with in all respects.
4.24 To Indemnify Against Claims

To take out and maintain at all times during the Term, with an insurer approved by the Landlord and which approval shall not be withheld in respect of an established insurer of good repute, a Policy or Policies of Insurance covering Public Liability in an amount not less than €10,000,000 (ten million euro) and Employers liability in respect of the Premises in each case in an amount of not less than €13,000,000 (Thirteen Million Euro) for each and every claim or series of claims arising from one occurrence and to ensure that each of the said policies contain an “Indemnity to Principals” clause in favour of the Landlord and to produce evidence that such policies are effected valid and subsisting (by way of broker’s certificate or otherwise) and the receipt for payment of the last premium thereon to the Landlord whenever reasonably required by the Landlord to do so on demand and to indemnify and keep indemnified the Landlord against all and any actions expenses costs claims damages and other liabilities whatsoever in respect of the injury or death of any person or damage to any property occurring during the Term howsoever arising and in particular without prejudice to the generality of the foregoing arising directly or indirectly out of:

4.24.1 the state of repair or condition of the Premises;
4.24.2 the making or exercising of any alteration to the Premises by the Tenant or any sub-tenant or state of repair or condition of such alteration;
4.24.3 the user of the Premises during the Term;
4.24.4 any work carried out or in the course of being carried out on the Premises by the Tenant or any sub-tenant;
4.24.5 any breach of the terms of this Lease on the part of the Tenant or any subtenant;
4.24.6 anything now or hereinafter attached to or projecting from the Premises,

BUT EXCLUDING any actions, proceedings, demands, claims, losses, costs, expenses, damages and liabilities solely and directly caused by any act or neglect on the part of the Landlord, their servants or agents.

4.25 Fire Safety Requirements

4.25.1 At all times during the Term to comply with all recommendations and all requirements of the appropriate fire or local authority and the insurers in respect of the safety and security of the Premises whether notified or directed to the Landlord and then to the Tenant or directly to the Tenant in relation to fire precautions and in particular the provision of fire screens and to comply with all the regulations from time to time made by the Landlord in relation to fire precautions and to indemnify the Landlord against any reasonably incurred and properly vouched costs and expenses in complying with any such requirement or written recommendation, and not to obstruct the access to or means of working any apparatus and appliance for that purpose for the time being installed in the Premises.

4.25.2 If required by the Landlord for the purposes of safety or where required to comply with the recommendations or the requirements of the Insurers of the Building to pay to the Landlord on demand the cost of providing and installing portable fire extinguishers fire hose reels or similar devices or at the Landlord’s option to install same at the Landlord’s direction and at the Tenant’s expense.

4.25.3 In the event of the Premises or any part thereof being damaged or destroyed by any of the Insured Risks to give immediate notice to the Landlord.
4.26 Not to Obstruct Pipes

Not to stop up or obstruct or permit or suffer to be stopped up or obstructed or to suffer any oil grease or other noxious or harmful matters or substances to enter the drains sewers gutters pipes channels and watercourses of the Premises and to employ such method for treating any deleterious effluent that may reasonably be required by the Landlord or be required by the Local Authority before permitting such effluent to enter any such drains sewers gutters pipes channels and watercourses.

4.27 Make Good Loss

To indemnify and make good all loss sustained by the Landlord in consequence of any breach by the Tenant or any underlessee of any covenant or condition on the Tenant’s part herein contained.

4.28 Stamp Duty

To pay the stamp duty tax chargeable on the original and counterpart of this Lease.

4.29 Yield Up

At the determination of the Term whether by effluxion of time re-entry notice surrender (whether by operation of law or otherwise) or by any other means whatsoever:

4.29.1 Subject to clause 4.29.2 and 4.29.3, to yield up the Premises with vacant possession in the condition set out in the Landlord’s Specification and in such state of good and substantial repair and condition as shall be in accordance with the continued performance and observance of the Tenant’s covenants contained in this Lease and otherwise in compliance with the covenants on the part of the tenant and conditions contained in this Lease.

4.29.2 Unless and to the extent that the Landlord gives the Tenant notice in writing to the contrary to remove all alterations or additions made to the Premises by or on behalf of the Tenant or any undertenant or occupier in a good and workmanlike manner and to procure that making good all damage caused to the Premises and any Nearby Property by such removal and/or reinstatement to the reasonable satisfaction of the Landlord.

4.29.3 To remove all chattels belonging to or used by the Tenant or any occupier and all tenant’s fixtures fittings and signs and other property belonging to the Tenant or any occupier.

4.29.4 To pay to the Landlord within fourteen days of written demand all fees and expenditure (including VAT not recoverable by the Landlord) reasonably incurred by the Landlord after the determination of the Term whether by effluxion of time re-entry notice surrender (whether by operation of law or otherwise) or by any other means whatsoever in repairing painting reinstating treating or decorating the Premises so as to put them into the condition commensurate with the due performance of the Tenant’s covenants contained in this Lease and additionally to pay to the Landlord within seven days of written demand mesne profits at the rate of the rents payable immediately prior to the determination of the Term whether by effluxion of time re-entry notice surrender (whether by operation of law or otherwise) or by any other means whatsoever and all additional rents due or payable under this Lease for the period reasonably required for such repairing painting reinstating treating and decoration of the Premises.

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4.30 Register of Companies

In the event that the Tenant or the Guarantor is at any time a company within the meaning of the Companies Acts, 1963 to 2013 to maintain its registration in the Companies Registration Office and not to permit same to lapse or to be struck off the Register of Companies.

4.31 Use of Premises outside Business Hours

4.31.1 The Landlord agrees that, subject to the provisions of this Clause 4.31, the Tenant shall have access to the Premises 24 hours each day during each day of the year.

4.31.2 If the Tenant shall desire, from time to time, to use the Premises outside the usual Business Hours of the Building, then (subject to the Landlord being able to provide such staff, services and security for the Building, as the Landlord may consider necessary) the Tenant shall be entitled to use and occupy the Premises and have access thereto on the following terms and conditions:

(a) the Tenant shall make prior arrangements with the Landlord or with the Surveyor or caretaker;

(b) the Tenant shall pay to the Landlord, on demand, the reasonable costs and expenses incurred by the Landlord attributable to the Tenant's access to and use of the Premises outside the usual business hours of the Building or a fair proportion of such costs to the extent that other tenants are using the Building during the same hours as the Tenant;

(c) the Tenant shall, in relation to all such access and use:

(i) use only such parts of the Common Areas as Landlord shall designate;

(ii) take all proper, necessary and required action to keep the Building secure;

(iii) abide by such rules and regulations as are from time to time prescribed by the Landlord (acting reasonably) for access, use and occupation of the Building outside usual business hours;

(iv) not permit or suffer any keys or other means of access to the Building to be in the hands of any person other than the trusted employees of Tenant or others first approved of in writing by Landlord (acting reasonably);

(v) indemnify and keep indemnified the Landlord against all losses, claims, liabilities, demands, proceedings, costs and expenses which are directly attributable to the Tenant’s access to and use of the Premises and the Common Areas outside usual business hours.

4.31.3 The Landlord hereby reserves the right to deny the Tenant access to the Building outside of Business Hours where the Tenant fails to comply with the provisions of this Clause 4.31.

4.32 BER Certificate

4.32.1 Where the Tenant prepares obtains commissions or procures a BER Certificate in respect of the Premises to provide to the Landlord a copy of that BER Certificate and any recommendation report and related information free of charge within seven days of receipt and (if not apparent from that copy) supply details to the Landlord of the reference number of that BER Certificate.

4.32.2 Not without the prior written consent of the Landlord to cause or permit a BER Certificate for the Premises to be invalidated or materially adversely affected.
4.32.3 To allow the Landlord to have access to all documentation data and information in the Tenant’s possession or control reasonably required to prepare any BER Certificate for the Premises;

4.32.4 To comply in respect of the Premises with any duty or obligation lawfully imposed under the EPB Regulations.

5 LANDLORD’S COVENANTS

The Landlord covenants with the Tenant:

5.1 Quiet Enjoyment

That the Tenant paying the rent hereby reserved and observing and performing the several covenants and stipulations herein on its part contained shall peaceably hold and enjoy the Premises during the Term without any interruption by the Landlord or any person rightfully claiming under or in trust for it.

5.2 Services

Subject to payment by the Tenant of all sums due from the Tenant from time to time in respect of the First Service Charge and the Second Service Charge to use all reasonable endeavours to provide or procure the provision of the services referred to in Part II of Schedule 2 and in part II of Schedule 6 PROVIDED ALWAYS that:

5.2.1 The Landlord shall not be liable to the Tenant in respect of any failure by the Landlord to perform any of the services referred to in this Lease, whether express or implied, unless and until the Tenant has notified the Landlord of such failure and the Landlord has failed within a reasonable time to remedy the same and then in such case the Landlord shall (subject to 5.2.2 and 5.2.3 below) by liable to compensate the Tenant for the actual (but not consequential, financial or other economic) loss or damage sustained by the Tenant after such reasonable time as elapsed; and

5.2.2 the Landlord shall be entitled at its discretion to cease to provide or vary any of the services referred to in Part II of Schedule 2 and in part II of Schedule 6 if any such service shall in the reasonable opinion of the Landlord cease to be for the benefit of the Building or any part thereof or become obsolete or redundant or cease to be cost effective; and

5.2.3 the Landlord shall not, in any circumstances, incur any liability for any failure or interruption in any of the services provided by the Landlord or any inconvenience or injury to person or property arising from such failure or interruption due to mechanical breakdown, failure or malfunction, overhauling, maintenance, repair or replacement, strikes, labour disputes, shortages of labour or materials, inclement weather or any cause or other circumstance beyond the control of the Landlord, provided that the Landlord shall use its reasonable endeavours to cause the service in question to be reinstated with the minimum of delay.

5.3 Insurance

5.3.1 Subject to the Landlord being able to effect such insurance and to such terms and conditions as are normally available from the insurance market, and subject further to reimbursement by the Tenant of the Insurance Rent from time to time, the Landlord hereby covenants with the Tenant to insue in the name of the Landlord the Building and the Premises and all Landlord’s fixtures and fittings therein and thereon.
(it being acknowledged by the Tenant that the Landlord has no obligation to insure the fixtures, fittings, equipment or other contents of the Tenant (or any sub-tenants) in the Premises and to keep the same insured in the full reinstatement cost (to be determined from time to time by the Landlord or its surveyors) and including an inflationary factor against damage by the Insured Risks PROVIDED HOWEVER that the Landlord shall not be responsible to the Tenant its servants agents licensees invitees or visitors for any injury death damage destruction financial or consequential loss whether to person or property due to the state and condition of the Building or the Premises or any part thereof or due to any act or default of any agent servant workman or other person authorised by the Landlord to enter the premises save to the extent to which the same may be insured against by the Landlord pursuant to the terms of this Lease.

5.3.2 The Landlord covenants to use reasonable endeavours:

(a) To obtain from the Landlord’s insurers a waiver of its subrogation rights (if any) against the Tenant in respect of the Premises so long as such a waiver is available in the insurance market from reputable insurers upon reasonably commercial terms;

(b) To cause the Landlord’s insurers to provide that the insurance policy or policies in respect of the Insured Risks contain a provision that the insurance is not invalidated by any change of occupancy or increase or risk taking place in or on the premises without the knowledge of the Landlord provided that the Landlord shall without undue delay upon the same coming to its knowledge give notice to the insurers and the Tenant shall pay any additional premiums as may be required from the date of such increase of risk so long as such provisions are available in the insurance market from reputable insurers upon reasonably commercial terms; and

(c) To notify the Tenant, as soon as reasonably practicable following implementation thereof, of any material changes to the insurance policy or policies in respect of the Insured Risks.

5.4 Reinstatement

In case the Premises or the Building or any part thereof shall be destroyed or damaged by any of the Insured Risks then (subject to the Landlord obtaining Planning Permission and all other necessary pertinent licences and approvals) and as often as shall happen to lay out all monies received in respect of such insurance as aforesaid as soon as practicable in or upon rebuilding, repairing or reinstating the Premises and the Building substantially in accordance with its existing plan and elevation in a good and substantial manner unless the relevant policy shall have been vitiates or rendered less than fully effective by any act, neglect, default or omission on the part of the Tenant PROVIDED ALWAYS that in the event of the Landlord being unable to procure reinstatement of the Premises substantially in accordance with its existing plan and elevation due to refusal of planning or other approvals consents or licences the Tenant agrees to surrender this Lease when called upon by the Landlord to do so whereupon the said insurance monies shall belong absolutely to the Landlord, but without prejudice to any claim by either party against the other in respect of any antecedent breach of covenant.
Provided Always and it is hereby expressly agreed as follows:

6.1 Re-entry

If:

6.1.1 the rents hereby reserved or any part thereof shall at any time be in arrear and unpaid for fourteen (14) days after the same shall have become due (whether any formal or legal demand therefor shall have been made or not); or

6.1.2 the Tenant shall at any time fail or neglect to commence to perform or observe any of the covenants, conditions or agreements herein contained and on its part to be performed and observed; or

6.1.3 the Tenant or the Guarantor (either or both being a body corporate, or if more than one body corporate then any one of them) shall compound or arrange with creditors or go into liquidation either compulsorily or voluntarily or has a winding-up petition presented against it or passes a winding-up resolution (other than in connection with a members voluntary winding up for the purposes of a solvent amalgamation or reconstruction first approved by the Landlord) or resolves to present its own winding-up petition or is wound-up (whether in Ireland or elsewhere) or a provisional liquidator is appointed or a receiver or statutory receiver or receiver and manager or administrator is appointed in respect of the Premises or any part of it or any of the assets or undertaking of the Tenant or the Guarantor; or

6.1.4 the Tenant or the Guarantor (either or both being a body corporate, or if more than one of them) permit or suffer to be appointed any examiner or interim examiner or administrator; or

6.1.5 the Tenant or the Guarantor shall be unable or admits its inability to pay its debts as they fall due; or

6.1.6 the Tenant or the Guarantor (either or both being a body corporate) shall be struck off the register in the Companies Registration Office or is dissolved and is not re-instated within 30 days; or

6.1.7 the Tenant or the Guarantor (either or both being an individual or firm or if more than one individual or firm then any one of them) commits an act of bankruptcy for the purposes of Section 7 of the Bankruptcy Act 1988 or shall become bankrupt or has a bankruptcy petition presented against him or it (in each case whether in Ireland or elsewhere) or is insolvent within the meaning of the Personal Insolvency Act 2012 or suffers any distress or execution to be levied on the Premises or compounds or arranges with his or its creditors or shall have a receiving order made against him or it; or

6.1.8 the Tenant or the Guarantor, being a Company incorporated outside the Republic of Ireland is the subject of any proceedings or event analogous to those hereinbefore referred to in its country of incorporation; or

6.1.9 the Tenant or the Guarantor (either or both being an individual) dies or becomes incapable of managing his affairs

then and in any such case it shall be lawful for the Landlord or any person or persons duly authorised by it into or upon the Premises or any part thereof in the name of the whole to re-enter and the Premises peaceably to hold and enjoy thenceforth as if this Lease had not been made without prejudice to any right of action or remedy of either party in respect of any antecedent breach of any of the covenants by either party hereinbefore contained.

6.2 Suspension of Rent

In the event of the Premises or any part thereof being damaged or destroyed by any of the Insured Risks from time to time so as to render the Premises unfit for occupation and use or inaccessible, then (unless in the case of damage or destruction by the Insured Risks the insurance monies shall be irrecoverable in whole or in part by reason solely or in
part of any act or neglect or omission of the Tenant) the rent hereby firstly reserved and the First Service Charge and the Second Service Charge or a fair proportion of them according to the nature and extent of the damage sustained shall be suspended until the Premises and the Building or any part thereof shall again be rendered fit for occupation and use and accessible or for the period of four years from the date of such destruction or damage whichever is the shorter and in the event of any dispute concerning the provisions of this sub-clause the same shall be determined by a single arbitrator in accordance with the provisions of the Arbitration Act 2010 and in the event that such reinstatement continues to be prevented after the said four years then either the Landlord or the Tenant shall be entitled at any time after the expiry of the said period of four years to determine this Lease by serving written notice to that effect on the other and upon service of which notice this Lease shall immediately cease and determine but without prejudice to any claim by either party against the other in respect of any antecedent breach hereof.

6.3 Pre-Emption

In the event that the Tenant wishes to assign its interest in the Lease or underlet the Premises at any time during the Term (save by way of permitted mortgage or charge to any bank or financial institution or by sharing occupation of the Premises in accordance with Clause 4.18.16 of this Lease) then the following provisions shall apply:

6.3.1 In such circumstances the Tenant shall serve on the Landlord a written notice to this effect (the “Sale Notice”) containing in full the terms on which the Tenant wishes to assign this Lease or as the case may be underlet the Premises, and offering to assign or underlet this Lease to the Landlord for the same consideration.

6.3.2 If the Landlord wishes to accept the offer made in the Sale Notice it will do so by serving on the Tenant a written notice (the “Acceptance Notice”) within 15 Working Days of receipt of the Sale Notice by the Landlord (the “Offer Period”). The Sale Notice will be deemed to have been received by the Landlord two Working Days after service by post and the next Working Day after service by hand. On the date of receipt by the Tenant of the Acceptance Notice (such notice will be deemed to have been received by the Tenant two Working Days after service by post and the next Working Day following service by hand) a binding contract shall then have been constituted between the Tenant and the Landlord for the assignment by the Tenant of its interest in this Lease or as the case may be the underletting by the Tenant of the Premises to the Landlord on the terms set out in the Sale Notice.

6.3.3 If the Landlord does not serve an Acceptance Notice during the Offer Period, then the Tenant may at any time during the period of five (5) months from the date of expiry of the Offer Period (the “Transfer Period”) market the Lease or seek to underlet the Premises with a view to securing an offer from a bona fide arms-length third party.

6.3.4 If the Tenant secures an offer from a bona fide arms-length third party which is consistent with or in excess of the offer contained in the Sale Notice then, but strictly subject to the other provisions of this clause 6.3 and the provisions of clause 4.18, the Tenant may assign its interest in this Lease or as the case may be underlet the Premises to such third party at any time during the Transfer Period on the terms of such offer PROVIDED ALWAYS that the Transfer Period shall be deemed to be automatically extended by the period equivalent to the time elapsing between the date of the Tenant’s application to the Landlord for consent to the assignment under clause 4.18 of this Lease and the date at which the Landlord formally responds to such application (whether by way of consent, refusal or request for further information).

6.3.5 If the offer obtained by the Tenant is less than that contained in the Sale Notice but the Tenant wishes nevertheless to accept it, then the Tenant shall serve on the Landlord a further written notice (the “Further Sale Notice”) containing full details
of such lower offer. If the Landlord wishes to accept the offer made in the Further Sale Notice it may do so by serving on the Tenant an Acceptance Notice within twelve (12) Working Days of the date of receipt by the Landlord of the Further Sale Notice. The Further Sale Notice will be deemed to have been received by the Landlord two Working Days after service by post and the next Working Day after service by hand. On the date of receipt by the Tenant of the Acceptance Notice (such notice will be deemed to have been received by the Tenant two Working Days after service by post and the next Working Day following service by hand or by confirmed fax) a binding contract shall then have been constituted between the Tenant and the Landlord for the assignment by the Tenant of its interest in this Lease or as the case may be the underletting of the Premises by the Tenant to the Landlord on the terms set out in the Further Sale Notice.

6.3.6 If the Landlord does not serve an Acceptance Notice within the period specified in clause 6.3.5 above following receipt of the Further Sale Notice, then the Tenant may at any time during the Transfer Period or a period of five months from the date of the Further Sale Notice (whichever period is longer), but strictly subject to the other terms and conditions of this clause 6.3 and of clause 4.18, assign its interest in this Lease or underlet the Premises to the relevant third party.

6.3.7 The procedure set out in this clause 6.3 will be repeated whenever the Tenant wishes to assign its interest in this Lease or underlet the Premises during the Term.

6.3.8 Whenever a binding contract for the sale of this Lease shall be constituted between the Tenant and the Landlord pursuant to this clause 6.3, the sale shall be governed by the provisions of the then current conditions (special and general) of sale as recommended by the Law Society of Ireland (which expression shall include any substitute or successive body).

6.4 Notices

6.4.1 Any demand or notice required to be given to, or served on the Tenant the Guarantor shall be duly and validly served if addressed to the Tenant or the Guarantor (as the case may be and, if the Tenant or the Guarantor constitutes more than one person, then addressed to any of them) and delivered personally, or sent by pre-paid registered or recorded delivery mail, or sent by facsimile transmission addressed (in the case of a company) to its registered office, or (whether a company or individual) to its last known address, or (in the case of a notice to the Tenant) to the Premises.

6.4.2 Any notice required to be given or served on the Landlord shall be sufficiently served if sent by pre-paid registered or recorded delivery mail, addressed:

(a) For as long as the Lessor’s interest herein is vested in the parties named as Landlord at the start of this Lease, to:

John Ronan and Castle Cove Property Developments Limited
Treasury Building
Lower Grand Canal Street
Dublin 2

or such other address as shall have been notified in writing to the Tenant for the purpose of service of notices on the Landlord; and

(b) otherwise, (in the case of a company) to the Landlord’s registered office, or (in the case of an individual) to its last known address.

6.4.3 A Notice sent by post shall be deemed to have been given forty-eight hours after the time of posting to the address to which it was sent.
6.5 Plans

The Plans annexed to this Lease and the details shown thereon shall be for the purpose of identification only and no warranty or condition expressed or implied shall be given or be deemed to be given in respect of such Plans or the details shown thereon or any matter or thing shown thereon or referred to.

6.6 Waiver of Right to Surrender

In case the Premises or any part thereof shall be destroyed or become ruinous and uninhabitable or incapable of beneficial occupation or enjoyment by or from any of the Insured Risks during the Term the Tenant hereby absolutely waives and abandons its rights (if any) to surrender this Lease under the provisions of Section 40 of the Landlord & Tenant Law Amendment, Ireland, Act 1860 or otherwise.

6.7 No Warranty

Nothing in this Lease contained shall be deemed to constitute any warranty by the Landlord that the Premises or any part thereof are authorised under the Planning Acts or otherwise for use for any specific purpose.

6.8 Consents, Agreements etc. of Landlord

No consent, agreement, variation, waiver or approval under this Lease or modification of this Lease shall bind the Landlord unless same is in writing duly signed and executed by a duly authorised officer of the Landlord (or by a person duly authorised in writing by the Landlord).

6.9 No Continuing Liability

The obligations of the Landlord under this Lease are personal to and shall be fully binding on the owner of the reversion to this Lease from time to time but shall not be enforceable against any person who has owned the reversion after that person has parted with all interest in it (except in relation to any period when that person was actually the owner of the reversion to this Lease).

6.10 Severance

In the event that any covenant or condition contained in this Lease shall be determined to be void or unenforceable in whole or in part for any reason whatsoever such unenforceability or invalidity shall not affect the enforceability or validity of the remaining covenants and conditions or parts of it and such void covenants or conditions shall be deemed to be severable from any other covenants and conditions or parts of it. If any covenant or provision contained in this Lease shall be determined to be void or unenforceable in whole or in part by reason of the area, scope, duration or type of restriction covered by the said covenant the same shall be given effect to in such reduced or modified form as may be decided as reasonable by any Court of competent jurisdiction.

6.11 No Set-Off

The Tenant shall not be entitled to make any counterclaim in respect of or set off against any payments due or payable to the Landlord under this Lease or otherwise and agrees to make all such payments in full irrespective of any set-off or any counterclaim of any nature.
6.12 No Waiver

If the Landlord accepts or demands the rents reserved by this Lease or other sums reserved or made payable under this Lease after the Landlord or its agents have become aware of or have had notice of any breach, non-performance or non-observance of any of the covenants on the part of the Tenant (or any undertenant or other occupier) or conditions contained in this Lease or any underlease, such acceptance of or demand for the rent or any other additional rents or sums will not waive any such breach, non-performance or non-observance or any of the Landlord’s rights or remedies under or by virtue of the Lease or otherwise (including without limitation any rights of forfeiture or re-entry) and the breach, non-performance or non-observance will be a continuing breach, non-performance or non-observance of the covenants or conditions in question so long as it continues and the acceptance of or demand for any rent reserved by this Lease or any additional rents or any such sums shall not be a defence in any action or proceeding by or on the part of the Landlord.

6.13 Jurisdiction

This Lease shall be governed by and construed in all respects in accordance with the Law of the Republic of Ireland and the Irish Courts shall have exclusive jurisdiction in relation to any disputes arising under or connected with this Lease and the Tenant and any Guarantor agree that any process may be served on them by leaving a copy of the relevant document at the Premises PROVIDED HOWEVER that the Landlord shall retain the right at its sole election to sue the Tenant and any Guarantor elsewhere including in the Courts of the Landlord’s and / or the Tenant’s and / or the Guarantor’s domicile.

6.14 Measurement

It is agreed that for the purposes of this Lease that the net lettable area of the Premises (excluding Car Spaces) is 10,266 square feet (ten thousand two hundred and sixty six square feet).

7 TENANT’S BREAK OPTION

7.1 The Tenant shall have the right to terminate this Lease on the Break Option Date subject to the following terms and conditions:

7.1.1 The Tenant shall give the Landlord no less than nine (9) months prior notice in writing of its intention to exercise the said right (the “Option Notice”) (and in this regard time shall be of the essence); and

7.1.2 On the Break Option Date the Tenant shall deliver the Premises to the Landlord free from any claims under the Landlord and Tenant Acts, 1967 – 2010 with no person (whether the Tenant or any other person) being in occupation of the Premises or any part of the Premises and on the basis that neither the Tenant nor any other person has any claim right or licence of any kind to possess or occupy the Premises or any part of the Premises; and

7.1.3 The Tenant shall continue to be responsible for the rents and all additional rents and all other payments and outgoings payable on foot of this Lease up to the Break Option Date; and

7.1.4 Any such termination shall be without prejudice to any antecedent breach by either the Landlord or Tenant of any of their respective covenants herein contained; and

7.1.5 Subject to the provisions of this Lease the Tenant shall pay to the Landlord all VAT (if any) which it is obliged to pay under the VAT Act and arising on the termination of the Lease.

7.2 Without prejudice to the provisions of Clause 7.1, the Tenant shall perform and observe all the covenants and conditions contained in this Lease and on its part to be performed and
observed up to the relevant Break Option Date, notwithstanding which, for the avoidance of doubt, failure of the Tenant to comply with this covenant shall not result in the loss of the break option provided for in Clause 7.1 save where such failure is a breach of one, several or all of clauses 7.1.1, 7.1.2, 7.1.3 or 7.1.5 which shall be a breach resulting in loss of the break option provided for in this clause 7.

7.3 In the event that and strictly subject to the Tenant serving a written notice (the "Statement Notice") on the Landlord no less than six (6) months prior to the Break Option Date (and in this regard time shall be of the essence) requiring the Landlord to send to the Tenant a written statement setting out such payments as must be made pursuant to clause 7.1.3 not later than 14 days before the Break Option Date (the "Statement") (to the intent that if the Tenant fails to send the Statement Notice, the Landlord will have no obligation to send the Statement), the Landlord will, not later than 14 days before the Break Option Date, send to the Tenant the Statement.

7.4 If the Lease is determined under this clause 7 above, the Landlord shall within a reasonable period of the Break Option Date repay to the Tenant a due proportion (on a daily basis) of any payments made under clause 7.1.3 paid in advance in respect of any period after the Break Option Date.

8 GUARANTOR COVENANTS

8.1 In consideration of this Lease having been entered into at its request, the Guarantor covenants with the Landlord, as a primary obligation, in the terms set out in Schedule 5.

8.2 The Guarantor irrevocably consents to any process in any legal action or proceedings arising out of or in connection with this Lease being served on it in accordance with the provisions of this Lease relating to the service of notices. Nothing contained in this Lease shall affect the right to serve process in any other manner permitted by law.

IT IS HEREBY CERTIFIED that for the purposes of Section 29 of the Companies Act, 1990 the Landlord and / or the Tenant and / or the Guarantor are not connected with one another in a manner which would require this transaction to be ratified by resolution of either.

IT IS HEREBY CERTIFIED for the purposes of Section 31 of the Companies Act, 1990 the Landlord and / or the Tenant and / or the Guarantor are not connected with one another in a manner which would require this transaction to be ratified by resolution of the Guarantor.

IN WITNESS of which this Lease has been executed as a Deed by the parties to it in the manner following and on the date and year first above written.

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SCHEDULE 1

Part I
Premises

ALL THAT portion of the Building being that part of the first floor thereof more particularly shown inlined in red on Plan 5 annexed hereto and including:

1. the internal plaster surfaces and finishes of all structural or load bearing walls and columns therein or which enclose the same, but not any other part of such walls or columns;

2. the entirety of all non-structural or non-load bearing walls and columns therein;

3. the inner half severed medially of the internal non load bearing walls (if any) that divide the same from other parts of the Building;

4. the floor finishes thereof and all carpets save that the lower limit of the Premises shall not extend to anything below the floor finishes except that raised floors and the cavity below them shall be included;

5. the ceiling finishes thereof, including all suspended ceilings (if any) and light fittings save that the upper limit of the Premises shall not extend to anything above the ceiling finishes except that the cavity above any suspended ceiling shall be included;

6. All window frames and window furniture and all glass in the windows and all doors, door furniture and door frames;

7. All sanitary and hot and cold water apparatus and equipment and the radiators (if any) therein and all fire fighting equipment and hoses therein exclusively serving the Premises;

8. All Conduits therein and exclusively serving the same;

9. All landlord’s fixtures, fittings and any equipment in or on the said lands premises and buildings; and

10. Any additions alterations and improvements to the Demised Premises.

Part II
Building

ALL THAT the Office Building situate at 1 Burlington Road and the rere of 40/42 Mespil Road in the City of Dublin as delineated and shown for the purpose of identification only on Plan 3 annexed hereto and thereon outlined in red.
Part III
Exceptions and Reservations

Excepting and reserving unto the Landlord and all other persons at any time authorised by them or any of them or otherwise entitled to the same rights as follows, exercisable in accordance with the provisions set out herein:

1. Full right and liberty to build upon and develop the Building and any adjoining premises or property now or hereafter belonging to the Landlord or to build upon or to extend in height or otherwise such premises from time to time adjoining or adjacent to the Premises or any building or any part thereof of which the Premises form part notwithstanding that the access of light and air to the Premises and the lights windows and openings thereof may be affected.

2. The free and uninterrupted passage and running of the Utilities through the Conduits which are now, or may at any time throughout the Term (or any extension or renewal thereof) be in, on, under or passing through the Premises.

3. Full right and liberty at all reasonable times to enter upon the Premises with or without appliances, equipment of any sort and workmen and others as often as may be necessary to view the state and condition of and to repair and maintain the Premises and (where same cannot reasonably be carried out at reasonable cost without accessing the Premises) clean alter renew remove or install such gutters pipes sewers drains wires conduits ducts flues and watercourses serving the Premises and adjoining premises and the Building (including the right if necessary to erect and maintain scaffolding).

4. The right to erect essential scaffolding for the minimum period necessary for the purpose of repairing or cleaning the Common Areas or any adjoining property or in connection with the exercise of any of the rights mentioned in this Schedule notwithstanding such scaffolding may temporarily interfere but not in any way materially prevent the proper access to and other enjoyment and use of the Premises.

5. The full rights of support and of shelter and protection to adjoining premises are at present enjoyed from the Premises.

6. All rights of light and air and other easements and rights now enjoyed by any other part or parts of the Building or any adjoining property over the Premises.

7. The full right and liberty to enter upon the Premises following the provision of at least 7 days prior written notice (save in the case of emergency when no notice is required) at any time during the Term in order to build on or into any party or other walls of the Premises the person or persons exercising such rights making good all damage to the structure of the Premises thereby occasioned.

8. The full right and liberty to enter upon the Premises at all reasonable times during the Term on provision of reasonable prior notice (save in cases of emergency when no notice shall be required) to gain access to the Premises and / or to the balcony or terrace (if any) forming part of the Premises as necessary for the purposes of carrying out the services described in Schedule 2.
9. The full right and liberty to develop the remainder of the Building or any adjoining property now or hereafter of the Landlord throughout the Term (or any extension or renewal thereof) in such manner as the Landlord shall think fit.

10. The airspace above the Premises.

11. The full right and liberty to close off the Common Areas or any part thereof for temporary period for the purpose of repairing, maintaining, replacing and renewing same.

12. The full right and liberty upon reasonable notice to the Tenant to re-locate the Car Spaces allocated to the Tenant to a different part of the Basement from time to time.

13. The right to regulate and control the use of the Common Areas in accordance with the principles of good estate management and in particular (but not by way of limitation) to:

   (a) vary or to change the use of, close or control access to the whole or any part of the Common Areas;

   (b) make regulations for the control, regulation and limitation of pedestrian or vehicular traffic in the Common Areas or in any part thereof and to erect such signs as may be appropriate;

   (c) the right to make rules and regulations in accordance with the principles of good estate management as follows:

      (i) for the control, regulation and limitation of the traffic vehicular and otherwise into and from and within the Building and in particular regulation for the delivery and storage of stocks and goods;

      (ii) for the storage, removal and disposal of waste;

      (iii) for the security of the Building as a whole or in respect of any part or parts;

      (iv) for emergency action and procedure;

      (v) for fire precautions.

Provided that the Landlord or the person exercising the foregoing rights shall exercise such rights in accordance with the principles of good estate management.

Part IV
Easements, rights and privileges

1. The full right for the Tenant, its servants, agents or licensees to use the Common Areas or any part thereof for all proper purposes in connection with the use and enjoyment of the Premises and the Car Spaces Provided always that at any time during the Term or any extension thereof the Landlord shall have full right and liberty in its absolute discretion to alter, stop up or block such Common Areas or any part or parts thereof, but not preventing the access to the Premises.
2. The right for the Tenant to use six (6) car spaces in the Basement in such positions as are allocated to the Tenant from time to time with reasonable prior notice (which shall mean two weeks prior written notice for the avoidance of doubt), the initial allocation being spaces numbered 40, 44, 45, 46, 47 and 48 (Basement -1) shown inlined in red on Plan No. 1 annexed hereto.

3. The free passage and running of utilities (subject to temporary interruption for repair, maintenance, renewal or replacement) to and from the Premises through the Conduits which are now laid or (throughout the Term (or any extension or renewal thereof)) shall be laid in, under or through other parts of the Building so far as any of the same are necessary for the reasonable use and enjoyment of the Premises.

4. The right of way for emergency purposes only over those parts of the Common Areas coloured blue on the Plans annexed hereto.

5. The right of way in the event of emergency only over that part of Block A shown shaded yellow on Plan 3 annexed hereto.

6. The right to use the existing bathrooms or toilet facilities and the existing lobby area on the first floor of the Building in common with any other occupational tenant located on the first floor of the Building.

7. Subject to:
   (a) The prior written consent of the Landlord and the Landlord’s prior approval of the size and location of any satellite dish equipment;
   (b) The Tenant paying all costs properly incurred by the Landlord in considering any application for such consent, including reasonable costs for professional advice in reviewing the application;
   (c) There being adequate and suitable space available on the roof of the Building at the time the Tenant makes an application for the Landlord’s consent;
   (d) The satellite dish equipment proposed to be installed by the Tenant having weight loading within acceptable limits;

The right for the Tenant at the Tenant’s own expense to install and maintain on the roof of the Building satellite dish equipment of a type acceptable to the Landlord and reasonably necessary for the Tenant’s use and enjoyment of the Premises, further subject to the Tenant complying with all requirements of the Landlord.

8. Subject to:
   (a) The prior written consent of the Landlord and the Landlord’s prior approval of the size and location of any such HVAC condensers;
(b) The Tenant paying all costs properly incurred by the Landlord in considering any application for such consent, including reasonable costs for professional advice in reviewing the application;

(c) There being adequate and suitable space available in the Basement on the wall beside the Car Spaces at the time the Tenant makes an application for Landlord’s consent;

(d) The HVAC condensers proposed to be installed by the Tenant having weight loading within acceptable limits;

The right for the Tenant at the Tenant’s own expense to install and maintain in the Basement one HVAC condenser of a type acceptable to the Landlord and necessary for the Tenant’s use and enjoyment of the Premises and the Car Spaces on the wall beside each (where possible and practicable) of the Car Spaces, further subject to the Tenant complying with all requirements of the Landlord.
Schedule 2

Part I

First Service Charge

1. The Tenant shall pay the Tenant’s Proportion of the First Service Charge on the days and in the manner and otherwise in accordance with the provisions hereinafter contained;

2. The amount of the First Service Charge shall be ascertained and certified by a certificate (hereinafter called “the certificate”) signed by the Landlord’s auditors or accountants (at the discretion of the Landlord) acting as experts and not as arbitrators annually and so soon after the end of the Landlord’s financial year as may be practicable and shall relate to such year in manner hereinafter mentioned;

3. The expression “the Landlord’s financial year” shall mean the period from the 1st day of January in each year to the 31st day of December of that same year or such other annual period as the Landlord may at its discretion from time to time determine as being that in which the accounts of the Landlord either generally or relating to the Building shall be made up;

4. A copy of the certificate for each such financial year shall be supplied by the Landlord to the Tenant on written request and without charge to the Tenant;

5. The certificate shall contain a summary of the Landlord’s said costs and expenses incurred by the Landlord during the Landlord’s financial year to which it relates together with a summary of the relevant details and figures forming the basis of the First Service Charge and the certificate (or a copy thereof duly certified by the person by whom the same was given) shall be conclusive evidence for the purposes hereof of the matters which it purports to certify save in circumstances of manifest error;

6. The expression “the costs and expenses incurred by the Landlord” as hereinbefore used shall be deemed to include not only those costs and expenses hereinbefore described which have been actually disbursed incurred or made by the Landlord during the year in question but also such reasonable part of all such costs and expenses hereinbefore described which are of a periodically recurring nature (whether recurring by regular or irregular periods) whenever disbursed incurred or made and whether prior to the commencement of the Term or otherwise including a sum or sums of money by way of reasonable provision for anticipated expenditure in respect thereof as the Landlord or its auditors or accountants (as the case may be) may in their discretion allocate to the year in question as being fair and reasonable in the circumstance;

7. The Tenant shall with every quarterly payment of rent reserved hereunder pay to the Landlord such sum in advance and on account of the First Service Charge as the Landlord or its auditors or accountants (as the case may be) shall specify at their reasonable discretion to be a fair and reasonable interim payment.

8. As soon as practicable after the signature of the certificate the Landlord shall furnish to the Tenant an account of the First Service Charge payable by the Tenant for the year in question due credit being given therein for all interim payments made by the Tenant in respect of the said year and upon the furnishing of such account showing such adjustment
as may be appropriate there shall be paid by the Tenant to the Landlord the amount of the First Service Charge as aforesaid or any balance found payable or there shall be allowed by the Landlord to the Tenant any amount which may have been overpaid by the Tenant by way of interim payment as the case may require;

9. It is hereby agreed and declared that nothing in this Clause or these presents contained shall disable the Landlord from maintaining an action against the Tenant in respect of non-payment of any such interim payment as aforesaid notwithstanding that the certificate had not been signed at the time of the proceedings.

10. It is hereby agreed and acknowledged that the First Service Charge payable by the Tenant hereunder shall include (meaning that the Reception Rent and Gym Rent shall be added to any other costs and expenses) the Tenant’s Proportion of the Reception Rent and the Gym Rent, such rents to be calculated in accordance with Clause 11 of this Part I Schedule 2.

11. From the date hereof until 31 July 2015:

   (i) the Reception Rent shall be calculated at a rate of €50.00 (fifty euro) per square foot; and

   (ii) the Gym Rent shall be calculated at a rate of €25.00 (twenty five euro) per square foot;

and thereafter each rent shall be adjusted on 1 August 2015 and on 1 August of every fifth year thereafter (each an “Additional Rent Review Date”). From each Additional Rent Review Date the Reception Rent and the Gym Rent payable shall be an amount equal to the Reception Rent and the Gym Rent each adjusted by reference to the Society of Chartered Surveyors / Investment Property Databank Office Rental Value Index (latest issue) (or in the event that such index no longer exists, by reference to the change in the cost of living as recorded by the Consumer Price Index), and by increasing or decreasing the Reception Rent and the Gym Rent payable on the day immediately preceding each Additional Rent Review Date in proportion to the rise or fall in the respective index figures between the previous Additional Rent Review Date and the current Additional Rent Review Date. From each Additional Rent Review Date until the next such review date the Tenant’s Proportion of the First Service Charge payable hereunder shall include the Tenant’s Proportion of the Reception Rent and the Gym Rent so adjusted.

12. Immediately upon receipt of each payment of the Tenant’s Proportion of the First Service Charge the Landlord may deduct therefrom and pay to itself for the Landlord’s own use and benefit and free from any claims of the Tenant that part of the said payment comprising the Tenant’s Proportion of the Reception Rent and the Gym Rent.

13. The inclusion of any of the Services in this Schedule shall not imply an obligation on the part of the Landlord or the Superior Landlord to provide such Service.

PROVIDED ALWAYS and notwithstanding anything herein contained it is agreed and declared that the provisions of sub-clause (8) of this Clause shall continue to apply notwithstanding the expiration or sooner determination of the term hereby granted but only in respect of the period down to such expiration or sooner determination of the Term; and
PROVIDED ALWAYS that the Landlord shall have full discretion acting in accordance with good estate management to determine whether any cost or expense should form part of the First Service Charge or the Second Service Charge.
Part II
(Services)

1. Repairing, renewing, replacing, maintaining, decorating and (where appropriate) cleaning, washing down, lighting, heating, servicing and (as and where necessary) renewing the Common Areas and, without prejudice to the generality of the foregoing, the lobby and toilet facilities on the first floor of the Building.

2. Maintaining and, when necessary, replacing carpets, furnishings and equipment in the Common Areas as the Landlord may reasonably determine and, without prejudice to the generality of the foregoing, the lobby and toilet faculties on the first floor of the Building.

3. Maintaining, repairing, operating, inspecting, servicing, overhauling, cleaning, lighting and (as and where necessary) renewing or replacing the air conditioning plant and equipment (if any) in the Building, and all plant machinery, apparatus and equipment within the Common Areas from time to time and, without prejudice to the generality of the foregoing, the lobby and toilet facilities on the first floor of the Building.

4. Maintaining, repairing, renewing, operating, inspecting, servicing, overhauling, cleaning and (as and where necessary) renewing or replacing all security and emergency systems for the Building.

5. Providing and maintaining and renewing name boards and signs in the main entrance hall Reception and any other parts of the Building and all directional signs and fire regulation notices and any flags, flag poles and television and radio aerials.

6. Providing and maintaining any dustbins or receptacles for refuse for the Building and the cost of collecting, storing and disposing of refuse.

7. The provision, maintenance, replacement, planting and cultivation of all landscaping and floral and artistic displays in the Common Areas.
8. Providing heating and cooling to the Premises in accordance with the following specification during the hours of 6.00am to 7.00pm Monday to Friday or such further hours which the Landlord may deem appropriate acting reasonably and such other times as the Tenant may request (at the Tenant’s cost) PROVIDED ALWAYS that the Landlord shall maintain heating and cooling to the Premises within 10% (Ten Per Cent) of the following parameters for chilled water, LPHW heating and ventilation as set out in this clause 8 of Part II of Schedule 2 (the “Parameters”), throughout the Term and rebalance affected systems or circuits, as appropriate, in the event that chilled water and LPHW heating and ventilation fall outside those Parameters:

**Chilled Water Design Parameters:**

<table>
<thead>
<tr>
<th>Floor</th>
<th>CHW Flowrate</th>
<th>Flow Temperature</th>
<th>Return Temperature</th>
<th>Calculated KW Load</th>
</tr>
</thead>
<tbody>
<tr>
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<td>11 deg C</td>
<td>86.2 kW</td>
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**LPHW Heating Design Parameters:**

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<th>Flow Temperature</th>
<th>Return Temperature</th>
<th>Calculated KW Load</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Floor Area 1</td>
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<td>82 deg C</td>
<td>71 deg C</td>
<td>94.25 kW</td>
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**Ventilation Design Parameters:**

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<th>Floor</th>
<th>Supply Air Volume Flowrate</th>
<th>Supply Air Temperature. (Summer)</th>
<th>Supply Air Temperature (Winter)</th>
<th>Return Air Volume Flowrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Floor Area 1</td>
<td>2.0 m³/s</td>
<td>18 deg C</td>
<td>18 deg C</td>
<td>2.0 m³/s</td>
</tr>
</tbody>
</table>

and providing heating and cooling to the Common Areas to the specification reflected in the mechanical and electrical specification set out in the Schedule 4 hereto to such temperatures as the Landlord may from time to time consider reasonably adequate between the hours of 7.00 am and 7.00 pm, Monday to Friday or such other hours which the Landlord may deem appropriate acting reasonably and for such periods of the year as the Landlord shall reasonably deem desirable.

9. Any other services relating to the Common Areas or any part thereof which the Landlord shall provide from time to time if, in its opinion such service is desirable or necessary in the interests of good estate management for the maintenance, upkeep or cleanliness of the Common Areas or for the benefit of all of the occupiers of the Building or otherwise in accordance with the principles of good estate management.

10. Providing a staffed reception in the Reception between the hours of 07:00 to 19:00 Monday to Friday excluding public holidays.

11. Providing security personnel in the Building between the hours of 07:00 to 19:00 Monday to Friday excluding public holidays.
Part III
(Expenditure)

1. The cost of management (including the collection of service charge) and of employing management agents, and accountants, auditors and surveyors in connection with surveying and accounting functions or the provision of services to the Common Areas.

2. The cost of employing (whether by the Landlord or any managing agents) such staff as the Landlord may in its absolute discretion consider appropriate for the performance of the services including reception and security personnel and all other expenditure ancillary to the employment of such persons including:
   (i) salaries, wages, insurances, pensions and pension contributions and other statutory contributions or levies;
   (ii) the provision of appropriate working clothing;
   (iii) the provision of appropriate vehicles, tools, equipment and apparatus for the proper performance of the services

3. All rates, taxes, assessments, duties, charges, impositions and outgoings whatsoever whether parliamentary, local or of any other description which may be assessed, charged, imposed or payable on or in respect of the whole or any part of the Common Areas.

4. The cost of the supply of electricity, gas, oil and other fuel for the provision of the services and the cost of any electricity generating, transforming, monitoring, metering and distribution plant apparatus and equipment in or serving the Common Areas.

5. Interest and fees in respect of money borrowed to finance the provision of the services and the cost referred to in this part of this Schedule or any of them.

6. The cost to the Landlord of abating any nuisance in respect of the Common Areas or any part of it.

7. Any legal costs and expenses incurred in the course of managing, operating and maintaining the Building and enforcing any covenants, conditions and regulations with respect thereto or complying with or otherwise taking action on any notice or orders in respect of the Common Areas and all legal and other costs and expenses incurred by the Landlord in enforcing the Landlord’s contractual rights pursuant to any collateral warranties issued to it in respect of any defect or disrepair in the Common Areas against any building contractor, subcontractors, architect, mechanical and electrical engineer and civil and structural engineer involved in the design and construction of the Building.

8. Any VAT (or any tax of a similar nature which may be substituted for or levied in addition to it) incurred by the Landlord on the cost referred to in this part of this Schedule or any of them save to the extent that such VAT (or other tax) is recoverable by the Landlord pursuant to the provisions of the VAT Act as amended from time to time.

9. Such sums as the Landlord shall, in its reasonable discretion, consider desirable to set aside from time to time for the purpose of providing for periodically recurring items of expenditure, whether recurring at regular or irregular intervals (such sums to be held in a separate interest bearing deposit account);
10. The Reception Rent;

11. The Gym Rent;

12. All other costs incurred in connection with provision of the services.
1 Interpretation

In this Schedule the following expressions shall have the following meanings respectively:

“Review Date” shall mean the day of 2019 and on the day of every fifth year thereafter any date so stipulated by virtue of paragraph 2.6 of this Schedule.

1.1 “Review Rent” shall mean the full yearly open market rent without any deduction whatsoever at which the Premises and the six (6) Car Spaces might reasonably be expected to be let at the relevant Review Date in the open market without a fine or premium and with vacant possession thereof by a willing landlord to a willing tenant for a term of fifteen (15) years computed from the relevant Review Date with an entitlement for the Tenant to terminate the said lease as of the tenth (10th) anniversary of the relevant Review Date and otherwise on the same terms and conditions in all other respects as this present Lease (save as to the amount of rent first reserved under this Lease but including the provisions for rent review) and upon the assumptions that:

(i) the Premises are provided to the Tenant as per the Landlord’s Specification (at the Landlord’s expense) and are fitted-out to a high quality standard and ready for immediate use and occupation.

(ii) in case the building of which the Premises form part or any part of it has been destroyed or damaged it has been fully restored.

(iii) all the obligations on the part of the Tenant and the Landlord contained in this Lease have been fully complied with.

(iv) no work has been carried out to the Premises which would diminish its rental value other than works to comply with statutory requirements.

(v) the Premises (excluding Car Spaces) comprise 10,266 square feet (ten thousand two hundred and sixty six square feet) of net lettable office space provided that, for the avoidance of doubt, the Premises has beneficial use of six (6) Car Spaces.

and there being disregarded:

(1) any effect on rent of the fact that the Tenant or any underlessee has been in occupation of the Premises and any goodwill attached to the Premises by reason of the carrying on thereof of the business of the Tenant or any underlessee;

(2) any effect on rent of any alterations to the Premises or any part thereof carried out by the Tenant or any underlessee with the consent of the Landlord at the Tenant’s or underlessee’s own expense (otherwise than in pursuance of any obligation to the Landlord) and carried out during the Term or pursuant to any Agreement for Lease;
any rent free concession reduced or abated rent or inducement of any kind which would or might be given to an incoming tenant on the grant of a lease of the Premises at the relevant Review Date to the intent that there shall be no reduction in the Review Rent to reflect such rent free concession reduced or abated rent or inducement or to compensate the Tenant for any absence of same;

1.2 "Surveyor" means an independent Chartered Surveyor experienced in the letting of office premises in the area in which the Premises are located.

2 Review Rent

The yearly rent first reserved and payable from each Review Date until the next Review Date (or, in the case of the period commencing on the last Review Date during the Term, until expiry of the Term) shall be the Review Rent.

2.1 Agreement or determination of the reviewed rent

If the Landlord and the Tenant shall not have agreed the Review Rent by the Review Date (or such extended period as may be agreed between the Landlord and the Tenant) the Landlord or the Tenant may by notice in writing to the the other party require the Review Rent to be determined by the Surveyor who shall be appointed forthwith by the Landlord and the Tenant or (in default of agreement at any time about his appointment) as nominated by the President for the time being of the Society of Chartered Surveyors on the application of either the Landlord or the Tenant.

2.2 Functions of Surveyor

2.2.1 Unless the Landlord elects that the Surveyor shall act as an expert he shall act as an Arbitrator and the arbitration shall be conducted in accordance with the Arbitration Act.

2.2.2 If the Surveyor is appointed as an expert he shall be required to give notice to the Landlord and the Tenant inviting each of them to submit to him within such time limits as he shall stipulate a proposal for the Review Rent and affording each party the opportunity to give in writing or otherwise a statement of reasons in support of its proposal and to make submissions in respect of each other's statement of reasons but the Surveyor shall not be bound thereby and shall make the determination in accordance with his own judgement.

2.2.3 If the Surveyor shall fail to determine the Review Rent within four months of his appointment or nomination or if he shall relinquish his appointment or die or if it shall become apparent that for any reason he will be unable or unfit to complete his duties hereunder a new Surveyor shall be appointed or nominated in his place in accordance with sub-clause 2.1 above.

2.3 Fees of Surveyor

The fees and expenses of the Surveyor including the costs of his nomination shall be in the award of the Surveyor (but this shall not preclude the Surveyor from notifying both parties of his total fees and expenses notwithstanding the non-publication at the time of his
2.4 Interim payments pending determination

If upon any such review the amount of the Review Rent shall not be ascertained or determined prior to the Review Date the Tenant shall continue to pay the rent payable hereunder immediately prior to the relevant Review Date (the “Current Rent”) until the Gale Day next following the ascertainment or determination of the Review Rent whereupon there shall be due as a debt: (i) payable on demand by the Tenant to the Landlord (if the Review Rent is higher than the Current Rent) a sum equal to the amount by which the Review Rent for the period since the Review Date exceeds the Current Rent for that period and in addition shall pay interest on said sums at the Base Rate from time to time from the Review Date until the date of actual payment; or (ii) by the Landlord to the Tenant (if the Review Rent is lower than the Current Rent payable before the Review Date) a sum equal to the amount by which the Current Rent for the period since the Review Date exceeds the Review Rent for that period and in addition shall pay interest on the said sums at the Base Rate from time to time from the Review Date until the date of actual payment.

2.5 Rent review memorandum

If upon any such review as aforesaid it shall be agreed or determined that the Review Rent is greater or less than the Current Rent the Landlord and the Tenant shall as soon as practicable after such determination or expiration complete and sign a written memorandum recording the Review Rent payable from the Review Date payable and the Tenant shall pay the Stamp Duty payable on such Memorandum.

2.6 Rent restrictions

In the event of either the Landlord or the Tenant being prevented or prohibited in whole or in part from determining the Review Rent by reason of any Legislation Statute Government Order or Decree or Notice then the date at which the review would otherwise have taken effect shall be deemed to be extended to permit and require such review to take place on the first date thereafter upon which Review Rent may be determined and if there shall be a partial prevention only there shall be a further review on the first date or dates as aforesaid.
1. **Guarantee**

The Guarantor hereby covenants with the landlord:

1.1 as a primary obligation that the Tenant or the Guarantor shall at all times during the Term (including any continuation or renewal of this Lease) duly perform and observe all the covenants on the part of the Tenant contained in this Lease, including the payment of the rents and all other sums payable under this Lease in the manner and at the times herein specified and the Guarantor hereby indemnifies the Landlord against all claims demands losses damages liability costs fees and expenses whatsoever sustained by the Landlord by reason of or arising in any way directly or indirectly out of any default by the Tenant in the performance and observance of any of its obligations or the payment of any rent and other sums arising before or after the expiration or termination of this Lease.

1.2 that the Guarantor is jointly and severally liable with the Tenant (whether before or after any disclaimer by a liquidator, official assignee or trustee in bankruptcy or other persons administering the assets of the Tenant or whether before or after any repudiation by an examiner or other persons administering the assets of the Tenant) for the fulfilment of all the obligations of the Tenant under this Lease and agrees that the Landlord in the enforcement of its rights hereunder, may proceed against the Guarantor as if the Guarantor was named as the Tenant in this Lease;

1.3 that the Guarantor shall not claim in any liquidation, bankruptcy, examinership, composition or arrangement of the Tenant in competition with the Landlord and shall remit to the Landlord the proceeds of all judgements and all distributions it may receive from any liquidator, examiner, official assignee, trustee in bankruptcy or supervisor of the Tenant and shall hold for the benefit of the Landlord all security and rights the Guarantor may have over assets of the Tenant whilst any liabilities of the Tenant or the Guarantor to the Landlord remain outstanding;

1.4 that the Guarantor shall:

1.4.1 if a liquidator, official assignee or trustee in bankruptcy or examiner shall disclaim, surrender or repudiate this Lease; or

1.4.2 if this Lease shall be forfeited; or

1.4.3 if the Tenant shall cease to exist,

on notice in writing given to the Guarantor by the Landlord within twelve (12) months after such disclaimer or other event accept from and execute and deliver to the Landlord a new lease of the Premises subject to and with the benefit of this Lease (if the same shall still be deemed to be extant at such time) for a term commencing on the date of the disclaimer or other event and continuing for the residue then remaining unexpired of the Term, such new lease to be at the cost of the Guarantor and to be at the same rents (the
initial annual rent being the same as that payable under this Lease at the time of any disclaimer or at the time of the happening of any event referred to above) and subject to the same covenants conditions and provisions as are contained in this Lease;

1.5 if following the occurrence of the events referred to in paragraph 1.4 the Landlord shall not require the Guarantor to take a new lease, the Guarantor shall nevertheless upon demand pay to the Landlord a sum equal to the rents and other sums that would have been payable under this Lease but for the disclaimer, forfeiture or other event in respect of the period from and including the date of such disclaimer, forfeiture or other event until the expiration of twelve (12) months therefrom or until the Landlord shall have granted a lease of the Premises to a third party (whichever shall first occur).

2. **Waiver by guarantor**

The Guarantor hereby waives any right to require the Landlord to proceed against the Tenant or to pursue any other remedy whatsoever which may be available to the Landlord before proceeding against the Guarantor.

3. **Postponement of participation by guarantor in security**

The Guarantor shall not be entitled to participate in any security held by the Landlord in respect of the Tenant’s obligations to the Landlord under this Lease or to stand in the place of the Landlord in respect of any such security until all the obligations of the Tenant or the Guarantor to the Landlord under this Lease have been performed or discharged.

4. **No release of guarantor**

4.1 None of the following, or any combination thereof, shall release, determine, discharge or in any way lessen or affect the liability of the Guarantor as principal debtor under this Lease or otherwise prejudice or affect the right of the Landlord to recover from the Guarantor to the full extent of this guarantee:

4.2 any neglect, delay or forbearance of the Landlord in endeavouring to obtain payment of the rents or any part or parts thereof and/or the amounts required to be paid by the Tenant in enforcing the performance or observance of any of the obligations of the Tenant under this Lease;

4.3 any refusal by the Landlord to accept rent tendered by or on behalf of the Tenant at a time when the Landlord was entitled (or would after the service of a notice under Section 14 of the 1881 Act have been entitled) to re-enter the Premises;

4.4 any extension of time given by the Landlord to the Tenant;

4.5 any variation of the terms of this Lease (including any reviews of the rent payable under this Lease) or the transfer of the Landlord’s reversion or the assignment of this Lease;

4.6 any change in the constitution, structure or powers of either the Tenant, the Guarantor or the Landlord or the liquidation, receivership, examinership, administration or bankruptcy (as the case may be) of either the Tenant or the Guarantor;
4.7 any legal limitation, or any immunity, disability or incapacity of the Tenant (whether or not known to the Landlord) or the fact that any dealings with the Landlord by the Tenant may be outside or in excess of the powers of the Tenant;

4.8 any other act, omission, matter or thing whatsoever whereby, but for this provision, the Guarantor would be exonerated either wholly or in part (other than a release under seal given by the Landlord).

5. **Benefit of guarantee**

This guarantee shall ensure for the benefit of the successors and assigns of the Landlord under this Lease without the necessity for any assignment thereof.

6. **Joint and several**

Where the Guarantor consists of two or more persons the covenants contained in this Lease shall be deemed to be made by such persons jointly and severally.
Schedule 6
Part I
Second Service Charge

1. The Tenant shall pay the Tenant’s Share of the Second Service Charge on the days and in the manner and otherwise in accordance with the provisions hereinafter contained;

2. The amount of the Second Service Charge shall be ascertained and certified by a certificate (hereinafter called “the certificate”) signed by the Landlord’s auditors or accountants (at the discretion of the Landlord) acting as experts and not as arbitrators annually and so soon after the end of the Landlord’s financial year as may be practicable and shall relate to such year in manner hereinafter mentioned;

3. The expression “the Landlord’s financial year” shall mean the period from the 1st day of January in each year to the 31st day of December of that same year or such other annual period as the Landlord may at its discretion from time to time determine as being that in which the accounts of the Landlord either generally or relating to the Building shall be made up;

4. A copy of the certificate for each such financial year shall be supplied by the Landlord to the Tenant on written request and without charge to the Tenant;

5. The certificate shall contain a summary of the Landlord’s said costs and expenses incurred by the Landlord during the Landlord’s financial year to which it relates together with a summary of the relevant details and figures forming the basis of the Second Service Charge and the certificate (or a copy thereof duly certified by the person by whom the same was given) shall be conclusive evidence for the purposes hereof of the matters which it purports to certify save in circumstances of manifest error;

6. The expression “the costs and expenses incurred by the Landlord” as hereinbefore used shall be deemed to include not only those costs and expenses hereinbefore described which have been actually disbursed incurred or made by the Landlord during the year in question but also such reasonable part of all such costs and expenses hereinbefore described which are of a periodically recurring nature (whether recurring by regular or irregular periods) whenever disbursed incurred or made and whether prior to the commencement of the Term or otherwise including a sum or sums of money by way of reasonable provision for anticipated expenditure in respect thereof as the Landlord or its auditors or accountants (as the case may be) may in their discretion allocate to the year in question as being fair and reasonable in the circumstance;

7. The Tenant shall with every quarterly payment of rent reserved hereunder pay to the Landlord such sum in advance and on account of the Second Service Charge as the Landlord or its auditors or accountants (as the case may be) shall specify at their reasonable discretion to be a fair and reasonable interim payment.

8. As soon as practicable after the signature of the certificate the Landlord shall furnish to the Tenant an account of the Second Service Charge payable by the Tenant for the year in question due credit being given therein for all interim payments made by the Tenant in respect of the said year and upon the furnishing of such account showing such adjustment
as may be appropriate there shall be paid by the Tenant to the Landlord the amount of the Second Service Charge as aforesaid or any balance found payable or there shall be allowed by the Landlord to the Tenant any amount which may have been overpaid by the Tenant by way of interim payment as the case may require;

9. It is hereby agreed and declared that nothing in this Clause or these presents contained shall disable the Landlord from maintaining an action against the Tenant in respect of non-payment of any such interim payment as aforesaid notwithstanding that the certificate had not been signed at the time of the proceedings.

10. Immediately upon receipt of each payment of the Tenant’s Proportion of the Second Service Charge the Landlord may deduct therefrom and pay to itself for the Landlord’s own use and benefit.

11. The inclusion of any of the Services in this Schedule shall not imply an obligation on the part of the Landlord or the Superior Landlord to provide such Service.

PROVIDED ALWAYS and notwithstanding anything herein contained it is agreed and declared that the provisions of sub-clause (8) of this Clause shall continue to apply notwithstanding the expiration or sooner determination of the term hereby granted but only in respect of the period down to such expiration or sooner determination of the Term; and

PROVIDED ALWAYS that the Landlord shall have full discretion acting in accordance with good estate management to determine whether any cost or expense should form part of the First Service Charge or the Second Service Charge.
Part II
(Services)

1. Repairing, renewing, replacing, maintaining, decorating and (where appropriate) cleaning, washing down, lighting, heating, servicing and (as and where necessary) renewing the First Floor Common Areas and, without prejudice to the generality of the foregoing, the lobby, fire alarm panel and toilet facilities on the first floor of the Building.

2. Maintaining and, when necessary, replacing carpets, furnishings, consumables and equipment in the First Floor Common Areas as the Landlord may in its absolute discretion determine and, without prejudice to the generality of the foregoing, the lobby, fire alarm panel and toilet facilities on the first floor of the Building.

3. Maintaining, repairing, operating, inspecting, servicing, overhauling, cleaning, lighting and (as and where necessary) renewing or replacing the air conditioning plant and equipment (if any) in the First Floor Floor Common Areas and all plant machinery, apparatus and equipment within the First Floor Common Areas from time to time and, without prejudice to the generality of the foregoing, the lobby, fire alarm panel and toilet facilities on the first floor of the Building.

4. Maintaining, repairing, renewing, operating, inspecting, servicing, overhauling, cleaning and (as and where necessary) renewing or replacing all security and emergency systems for the First Floor Common Areas.

5. Providing and maintaining any dustbins or receptacles for refuse for the Building and the cost of collecting, storing and disposing of refuse.

6. The provision, maintenance, replacement, planting and cultivation of all landscaping and floral and artistic displays in the First Floor Common Areas.

7. Providing heating and cooling to the First Floor Common Areas to the specification reflected in the mechanical and electrical specification set out in the Schedule 4 hereto to such temperatures as the Landlord may from time to time consider reasonably adequate between the hours of 7.00 am and 7.00 pm, Monday to Friday or such other hours which the Landlord may deem appropriate acting reasonably and for such periods of the year as the Landlord shall reasonably deem desirable.

8. Any other services relating to the First Floor Common Areas or any part thereof which the Landlord shall provide from time to time if, in its opinion such service is desirable or necessary in the interests of good estate management for the maintenance, upkeep or cleanliness of the First Floor Common Areas or for the benefit of all of the occupiers of the first floor or otherwise in accordance with the principles of good estate management.

9. Providing and maintaining name boards and signs in the entrance hall and any other parts of the first floor of the Building and all directional signs and fire regulation notices and any flags, flag poles and television and radio aerials.
Part III
(Expenditure)

1. The cost of management (including the collection of the Second Service Charge) and of employing management agents, and accountants, auditors and surveyors in connection with surveying and accounting functions or the provision of services to the First Floor Common Areas.

2. The cost of employing (whether by the Landlord or any managing agents) such staff as the Landlord may in its absolute discretion consider appropriate for the performance of the services referred to in this Schedule including reception and security personnel and all other expenditure ancillary to the employment of such persons including:
   (i) salaries, wages, insurances, pensions and pension contributions and other statutory contributions or levies;
   (ii) the provision of appropriate working clothing;
   (iii) the provision of appropriate vehicles, tools, equipment and apparatus for the proper performance of the services referred to in this Schedule.

3. All rates, taxes, assessments, duties, charges, impositions and outgoings whatsoever whether parliamentary, local or of any other description which may be assessed, charged, imposed or payable on or in respect of the whole or any part of the First Floor Common Areas.

4. The cost of the supply of electricity, gas, oil and other fuel for the provision of the services referred to in this Schedule and the cost of any electricity generating, transforming, monitoring, metering and distribution plant apparatus and equipment in or serving the First Floor Common Areas.

5. Interest and fees in respect of money borrowed to finance the provision of the services referred to in this Schedule and the cost referred to in this part of this Schedule or any of them.

6. The cost to the Landlord of abating any nuisance in respect of the First Floor Common Areas or any part of it in so far as the same is not the liability of any one tenant or occupier of the Building.

7. Any legal costs and expenses incurred in the course of managing, operating and maintaining the First Floor Common Areas and enforcing any covenants, conditions and regulations with respect thereto or complying with or otherwise taking action on any notice or orders in respect of the First Floor Common Areas and all legal and other costs and expenses incurred by the Landlord in enforcing the Landlord’s contractual rights pursuant to any collateral warranties issued to it in respect of any defect or disrepair in the First Floor Common Areas against any building contractor, sub-contractors, architect, mechanical and electrical engineer and civil and structural engineer involved in the design and construction of the Building.

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8. Any VAT (or any tax of a similar nature which may be substituted for or levied in addition to it) incurred by the Landlord on the cost referred to in this part of this Schedule or any of them save to the extent that such VAT (or other tax) is recoverable by the Landlord pursuant to the provisions of the VAT Act as amended from time to time.

9. Such sums as the Landlord shall, in its absolute discretion acting reasonably, consider desirable to set aside from time to time for the purpose of providing for periodically recurring items of expenditure, whether recurring at regular or irregular intervals (such sums to be held in a separate interest bearing deposit account);

10. All other costs properly incurred in connection with provision of the services referred to in this Schedule.
SIGNED AND DELIVERED
as a deed by JOHN RONAN
in the presence of:

/s/ John Ronan

PRESENT when the Common Seal of
CASTLE COVE PROPERTY DEVELOPMENTS
LIMITED was affixed hereto as a deed

/s/ John Ronan
Director

/s/ Jodi Ronan
Director / Secretary

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PRESENT when the Common Seal of HORIZON PHARMA SERVICES LIMITED (THE TENANT) was affixed hereto as a deed:

/s/ Patrick Ashe
Director

/s/ David Kelly
Director / Secretary

PRESENT when the Common Seal of HORIZON PHARMA PUBLIC LIMITED COMPANY (THE GUARANTOR) was affixed hereto as a deed:

/s/ Timothy P. Walbert
Director

/s/ Paul W. Hoelscher
Director / Secretary

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This ASSET PURCHASE AGREEMENT (as amended from time to time, the “Agreement”), dated as of May 17, 2012 (the “Agreement Date”), is made and entered into by and among Vidara Therapeutics International Limited, an Irish company (“Purchaser”), Vidara Therapeutics Holdings LLC, a Delaware limited liability company (“Parent”), Vidara Therapeutics Research Limited, an Irish company (“Opco”) and InterMune, Inc., a Delaware corporation (“Seller”). Purchaser, Parent, Opco and Seller are sometimes collectively referred to herein as the “Parties” and separately as a “Party.”

RECITALS

WHEREAS, Seller is a biopharmaceutical company focused on developing and commercializing innovative therapies in pulmonology and hepatology;

WHEREAS, Purchaser is a biopharmaceutical company focused on the development and commercialization of differentiated specialty products to treat unmet medical needs;

WHEREAS, Seller has determined that the sale of certain products and product related intellectual property rights at this time is consistent with its current business strategy;

WHEREAS, Purchaser has determined that the acquisition of those certain products and product related intellectual property rights at this time is consistent with its current business strategy;

WHEREAS, Purchaser is a wholly-owned subsidiary of Parent and Opco is a wholly-owned, indirect subsidiary of Purchaser; and

WHEREAS, Seller desires to sell such products and product-related intellectual property rights to Purchaser, and Purchaser desires to purchase such products and product-related intellectual property rights from Seller, on the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the promises, representations, warranties, covenants and agreements contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound hereby, agree as follows:

ARTICLE I
DEFINITIONS

Section 1.1 Defined Terms. For the purposes of this Agreement, the following words and phrases shall have the following meanings whether in the singular or the plural:

“AAA” shall have the meaning set forth in Section 10.12(a).

“Acquisition Proposal” shall mean an indication of interest, offer or proposal to acquire Seller’s right, title and interest in and to all or any substantial portion of the Purchased Assets in
a single transaction or series of related transactions (other than the transactions provided for in this Agreement).

“Additional Intellectual Property” shall have the meaning set forth in Section 8.15(c).

“Affiliate” shall mean with respect to any Person, any other Person which controls, is controlled by, or is under common control with such Person. For purposes of this definition, a Person shall be regarded as in control of another Person if it owns or controls, directly or indirectly, (i) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) entitled to vote for the election of directors or otherwise having the power to vote on or direct the affairs of such Person; and (ii) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) (or the maximum ownership interest permitted by law) of the equity interest or the power to direct the management and policies of such non-corporate entities.

“Agreement” shall have the meaning set forth in the first paragraph of this Agreement.

“Agreement Date” shall mean the date set forth in the first paragraph of this Agreement.

“Allocation Schedule” shall have the meaning set forth in Section 2.8.

“Alternate Seller Bank Account” shall have the meaning set forth in Section 2.1(b)(ii)(A).

“Ancillary Agreements” shall mean the Assignment and Assumption Agreements, the Bills of Sale, the Domain Name Assignment Agreement, the Patent Assignment Agreement and the Transition Services Agreement.

“Annual Period” shall mean a twelve (12) month period measured from the Closing Date, or an anniversary of the Closing Date, to the next anniversary of the Closing Date.

“Antitrust Regulations” shall mean the HSR Act and any other Applicable Laws or regulations relating to antitrust or competition.

“Applicable Law” shall mean all applicable provisions of all statutes, Laws, rules, regulations, administrative codes, ordinances, decrees, orders, decisions, guidance documents, injunctions, awards, judgments, and permits and licenses of or from Governmental Authorities relating to or governing the use or regulation of the subject item.

“Assignment and Assumption Agreements” shall mean those certain assignment and assumption agreements in the form attached hereto as Exhibit B.

“Assumed Contracts” shall mean (i) the Contracts identified on Schedule 1.1(d) and (ii) any purchase orders for Product received by Seller or its Affiliates prior to the Closing Date, but not shipped prior to 11:59 p.m., PDT, on the day prior to the Closing Date.

“Assumed Liabilities” shall mean the Liabilities set forth in Section 2.3.
“B-I Purchase Orders” shall mean (i) that certain Purchase Order No. PO10395, dated as of May 2, 2012, submitted by Seller to Boehringer-Ingelheim and (ii) that certain Purchase Order No. PO10396, dated as of May 2, 2012, submitted by Seller to Boehringer-Ingelheim, both of which are appended hereto as Exhibit F.

“B-I Supply Agreement” shall mean the Supply Agreement between Seller and Boehringer-Ingelheim dated as of June 29, 2007, as amended and restated as of May 15, 2012, providing for the manufacture and supply of the Product, attached as part of Exhibit E.

“Basket Amount” shall have the meaning set forth in Section 9.2(a).

“Bills of Sale” shall mean those certain bills of sale in the forms attached hereto as Exhibit A.

“Boehringer-Ingelheim” shall mean Boehringer Ingelheim Austria GmbH or its successor-in-interest Boehringer Ingelheim RCV GmbH & Co KG.

“Business Day” shall mean a day, which is not a Saturday, a Sunday, or a statutory holiday in the United States.

“Cap” shall have the meaning set forth in Section 9.2(c).

“Chargebacks” shall mean chargebacks and similar payments to wholesalers and other distributors in connection with the Product.

“Closing” shall have the meaning set forth in Section 2.5.

“Closing Cash Payment” shall have the meaning set forth in Section 2.1(b)(i).

“Closing Date” shall have the meaning set forth in Section 2.5.


“Commercial Rebates” shall mean rebates to commercial customers.

“Competing Product” shall mean any product that is or is being developed to be a generic equivalent of, a generic formulation of, biosimilar or interchangeable with the Product where “biosimilar” and “interchangeable” shall have the meaning ascribed to them under the Biosimilars Act 42 USC 262(i).

“Confidentiality Agreement” shall have the meaning set forth in Section 10.1(a).

“Confidential Information” shall mean Purchaser Confidential Information and Seller Confidential Information.

“Consent” shall have the meaning set forth in Section 2.9.

“Contract” shall mean any agreement, contract, lease, consensual obligation, promise, or undertaking (whether written or oral), to which Seller or any of its Affiliates is a party (i) that
relates solely or primarily to the Product, the Product Business, the Purchased Assets or the Assumed Liabilities, or (ii) that, to the extent related to the Product, is necessary for the conduct of the Product Business as conducted by Seller.

“Controlled” shall mean, with respect to any of the Inventory, any of the Product Intellectual Property and any of the Product Records, that is owned or licensed (as licensor or licensee) by Seller and/or any of its Affiliates, and in which Seller has the legal authority or right to grant, convey, transfer and assign to Purchaser, all of Seller’s (and any of its Affiliates’) rights, titles and interests therein and thereto.

“Copyright” shall mean U.S., international or foreign copyrights, including any and all Copyright Registrations and Applications therefor, and all exclusive rights under all such copyrights, for, in and to, or otherwise based upon any and all documents, website content, data, artwork, advertising materials, product packaging, product labels, product packaging inserts and product instructions.

“Copyright Registrations and Applications” shall mean U.S., international or foreign copyright registrations, recordations and applications, and any and all renewals, extensions and reversions thereof, for which a registration or serial number may be, has been or will be assigned by the relevant Governmental Authority.

“Dispute” shall have the meaning set forth in Section 10.12(a).

“Domain Name Assignment Agreement” shall mean that certain domain name and webpages assignment agreement in the form attached hereto as Exhibit G.

“Domain Names” shall mean any and all Internet domain names, websites and URLs, and any and all applications and registrations therefor.

“Earnout” shall have the meaning set forth in Section 2.1(b)(ii)(A).

“Encumbrance” shall mean claims, security interests, liens, pledges, charges, escrows, options, proxies, rights of first refusal, preemptive rights, covenants not to sue, mortgages, hypothecations, assessments, prior assignments, reversionary rights, reversionary titles, reversionary interests, title retention agreements, conditional sales agreements, indentures, deeds of trust, leases, levies or security agreements of any kind whatsoever, or any other agreements to give any of the foregoing in the future, imposed upon the subject property or item.

“Environmental Law” shall mean any applicable Law relating directly or indirectly to (i) the protection of the environment (including air, water vapor, surface water, groundwater, drinking water supply, surface or subsurface land), (ii) occupational health and safety or (iii) the exposure to, or the use, storage, recycling, treatment, generation, transportation, processing, handling, labeling, recycling, release or disposal of, hazardous materials.

“Exchange Act” shall have the meaning set forth in Section 3.13(a).

“Excluded Assets” shall mean all assets and properties (other than the Purchased Assets) of Seller and its Affiliates, including without limitation the Excluded Data and Materials.
“Excluded Claim” shall mean any dispute, controversy or claim arising from or related to (i) any of the representations, warranties, covenants, agreements and/or provisions set forth in Sections 3.10, 8.14 and/or 8.15 of this Agreement, and any inaccuracy or breach thereof, (ii) any of the representations, warranties, covenants, agreements and/or provisions of this Agreement that relate to the Product Intellectual Property and any inaccuracy or breach thereof and (iii) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

“Excluded Data and Materials” shall mean all case report forms, data, reports, publications, abstracts and other information, materials and patient samples generated by or for Seller or its Affiliates in the conduct of the clinical development of Interferon Gamma-1b for the treatment of patients with idiopathic pulmonary fibrosis.

“Excluded Liabilities” shall have the meaning set forth in Section 2.4(a).

“FDA” shall mean the United States Food and Drug Administration or any successor organization.

“Financial Data” shall have the meaning set forth in Section 3.13(c).

“GAAP” shall mean United States generally accepted accounting principles.

“Genentech License” shall mean the License Agreement for Interferon Gamma between Connectics Corporation and Genentech, Inc. dated as of May 5, 1998, as amended.

“Genentech Patents” shall mean the Patent Rights granted pursuant to the Genentech License.

“Governmental Authority” shall mean the government of the applicable country in the Territory and any state, province, municipality or other political subdivision thereof or therein, or any court, tribunal, judiciary body, agency, department, board, instrumentality, panel, dispute resolution agency, patent office, trademark office, copyright office and any official authority or commission (including regulatory and administrative bodies) of any of the foregoing.

“HIPAA” shall have the meaning set forth in Section 3.15(b).

“HITECH” shall have the meaning set forth in Section 3.15(b).

“HSR Act” shall have the meaning set forth in Section 8.1(b).

“Indemnification Claim Notice” shall have the meaning set forth in Section 9.4.

“Indemnified Party” shall mean the Seller Indemnified Parties or the Purchaser Indemnified Parties, as applicable, in accordance with the terms of this Agreement.

“Indemnifying Party” shall mean the Purchaser, Parent or the Seller, as applicable, in accordance with the terms of this Agreement.

“Interferon Gamma-1b” shall mean the amino acid sequence and description set forth on Exhibit 1 to the Seller Disclosure Schedule.

“Inventory” shall mean the Product, and all active pharmaceutical ingredients which are used solely or primarily in the production of the Product, that are owned or Controlled by Seller or its Affiliates on the Closing Date for Seller’s marketing and sale and which (i) are of a quality usable and salable in the ordinary course of business and (ii) in the case of the Product, comprise all unsold lots.

“IPF Patient Data” shall mean data accessible through Seller’s Product regulatory safety database (e.g., the annual safety update reports provided by Seller to the FDA contained therein) and the ARISg global safety database maintained by Seller, which data exists at the time such databases are transferred by Seller to Purchaser after the Closing and which may include, among other things, safety data generated by or for Seller or its Affiliates in the conduct of the clinical development of Interferon Gamma-1b for the treatment of patients with idiopathic pulmonary fibrosis; provided, however, that for purposes of clarity, IPF Patient Data shall not be deemed to include any case report forms, data (other than the data accessible through Seller’s regulatory safety database and the ARISg global safety database described herein), reports (other than the annual safety update reports described herein), publications, abstracts and other information, materials and patient samples generated by or for Seller or its Affiliates in the conduct of the clinical development of Interferon Gamma-1b for the treatment of patients with idiopathic pulmonary fibrosis.

“IRS” shall mean the United States Internal Revenue Service.

“Know-How” shall mean confidential or proprietary information, including, without limitation, Trade Secrets, inventions (whether or not patentable), discoveries, developments, improvements, enhancements, concepts, ideas, methods, processes, designs, schematics, drawings, formulae, data, technical data and information, specifications, instructions, research and development information, technology and databases.

“Knowledge of Purchaser” or “to Purchaser’s Knowledge” or any similar such statement shall mean Bala Venkataraman, Virinder Nohria, Rick McElheny and Brian Anderson, or any executive officer or director of Purchaser or Parent, directly involved on behalf of Purchaser or Parent in the transactions contemplated herein, has or had actual knowledge, or such knowledge as would be reasonably expected to have been obtained after reasonable inquiry, of a fact or matter.

“Knowledge of Seller” or “to Seller’s Knowledge” or any similar such statement shall mean Lawrence Kahn, Yip Fong Chia, Carla Fiankin, Sandy Mohan, Frank Zampella, and Bruce Tomlinson, or any executive officer of Seller directly involved in the Product Business, has or had actual knowledge, or such knowledge as would be reasonably expected to have been obtained after reasonable inquiry, of a fact or matter.
“Law” shall mean any foreign, federal, state or local law, statute or any rule, or regulation promulgated by any Governmental Authority.

“Liability” shall mean, collectively, any liability, indebtedness, guaranty, endorsement, claim, loss, damage, deficiency, cost, expense, obligation, responsibility, or product liability, whether fixed or unfixed, known or unknown, choate or inchoate, liquidated or unliquidated, secured or unsecured, direct or indirect, matured or unmatured, or absolute, contingent or otherwise.

“Losses” shall mean any and all losses, damages, Liabilities, deficiencies, claims, proceedings, causes of action, costs (including reasonable out of pocket costs of investigation) and expenses, including interest, diminution in value, penalties, settlement costs, judgments, awards, fines, costs of mitigation, losses in connection with any Environmental Law (including any clean up or remedial action), court costs and fees (including reasonable attorneys’ fees and expenses).

“Material Adverse Effect” shall mean any change, circumstance, event or effect that has had or is reasonably likely to have in the future, individually or in the aggregate, a material adverse effect on (i) the condition (financial or otherwise) or results of operation of the Product Business or the Purchased Assets or (ii) the ability of Seller to consummate the transactions contemplated by this Agreement; provided that no changes, circumstances, events or effects resulting from or arising out of the following shall be taken into account in determining whether a Material Adverse Effect has occurred: (a) the public announcement of the entering into of this Agreement or the other Ancillary Agreements or the pendency of the transactions contemplated hereby or thereby (including any cancellation or delay of customer orders, any reduction in sales, any disruption in supplier, partner or similar relationships or any loss of employees), (b) the performance by Seller of any action, or the failure to take any action, in each case at Purchaser’s written request (including email) pursuant to this Agreement or the other Ancillary Agreements, (c) general economic conditions, (d) general conditions in the industry in which the Product Business is conducted, (e) changes in GAAP or Applicable Law which have general application, (f) the failure of the business to meet any internal projections or forecasts of revenue or earnings (provided that the underlying cause of such failure shall be taken into account unless such cause is otherwise included in clause (a) through (e), or (g)), or (g) fire, flood, tornado, earthquake or other acts of nature, acts of terrorism or sabotage, war, regional, national or international calamity, military action or any other similar event or any escalation or worsening thereof after the date hereof, except to the extent, in the case of the foregoing clauses (c) through (e), such changes, circumstances, events or effects referred to therein have a materially disproportionate impact on the Product Business relative to the industry in which the Product Business competes as a whole.

“Opco” shall have the meaning set forth in the first paragraph of this Agreement.

“Parent” shall have the meaning set forth in the first paragraph of this Agreement.

“Party” or “Parties” shall have the meaning set forth in the first paragraph of this Agreement.
“Patent Assignment Agreement” shall mean that certain patent assignment agreement in the form attached hereto as Exhibit D.

“Patent Rights” shall mean U.S., international or foreign patents, provisional patent applications, patent applications, design registrations, design registration applications, industrial designs, industrial design applications and industrial design registrations, including any and all divisions, continuations, continuations-in-part, extensions, substitutions, renewals, registrations, revalidations, reexaminations, reissues or additions, including supplementary certificates of protection, of or to any of the foregoing items.

“Permitted Encumbrances” shall mean (i) Encumbrances for Taxes, assessments and other governmental charges not yet due and payable or, if due, either (a) not delinquent or (b) being contested in good faith by appropriate proceedings, (ii) mechanics’, workmen’s, repairmen’s, warehousemen’s, carriers’ or other similar Encumbrances, including all statutory Encumbrances, arising or incurred in the ordinary course of business and not yet delinquent or, (iii) Encumbrances that do not materially affect the ownership, value or use of the underlying Purchased Asset for the purpose it is being utilized by Seller or its Affiliates on the Closing Date.

“Person” shall mean any natural person, corporation, unincorporated organization, partnership, association, joint stock company, joint venture, limited liability company, trust or government, or any agency or political subdivision of any government, or any other entity.

“Post-Closing Tax Period” shall have the meaning set forth in Section 8.8(c).

“Pre-Closing Tax Period” shall have the meaning set forth in Section 8.8(c).

“Proceeding” shall mean any litigation, claim, action, dispute, lawsuit, arbitration, dispute resolution process, cancellation proceeding, opposition proceeding, concurrent use proceeding, reexamination proceeding, nullification proceeding, interference proceeding, priority contest, challenge, protest, inquiry, change demand, order, judgment, hearing, assessment, or any other proceeding (whether civil, criminal, administrative or investigative), commenced, brought, conducted, or heard by or before any Governmental Authority or arbitrator.

“Product” shall mean the finished pharmaceutical product containing Interferon Gamma-1b in the formulation approved by the FDA for the reduction of the frequency and severity of serious infections related to chronic granulomatous disease and delaying time to disease progression in patients with severe, malignant osteopetrosis and sold by Seller under the Actimmune® trademark prior to the Closing.

“Product Business” shall mean the manufacturing, using, developing, promoting, advertising, marketing, distributing, selling, offering to sell, importing and/or exporting of the Product in the Territory.

“Product Copyrights” shall mean any and all Copyrights (including, without limitation, any and all Copyright Registrations and Applications listed on Schedule 1.1(c)) that are Controlled by Seller and/or any of its Affiliates and that relate solely to the Product and/or the Product Business.
“Product Domain Names” shall mean any and all active or inactive Domain Names, that are Controlled by Seller and/or any of its Affiliates and that relate solely to the Product and/or the Product Business, as identified on Schedule 1.1(c).

“Product Intellectual Property” shall mean the Product Copyrights, Product Domain Names, Product Know-How, Product Patents, Product Trademarks and Product Trade Secrets, including, without limitation, each of the foregoing as listed on Schedule 1.1(c).

“Product Know-How” shall mean any and all Know-How that is Controlled by Seller and/or any of its Affiliates and that relates primarily to the Product and/or the Product Business, excluding the Excluded Data and Materials.

“Product Master Cell Bank” or “PMCB” shall mean collectively the following cell banks relating to the Product or the Product Business: (i) the cell bank stored at Fisher BioServices Inc. located at 14665 Rothgeb Dr., Rockville, Maryland, 20850; and (ii) the working cell bank W3110 pHF CYC5, in each of which Seller or its Affiliates have ownership or other rights or interests, whether contractual or otherwise, therein or with respect thereto.

“Product Master Cell Bank Records” shall mean all records and associated agreements with third party providers relating to the development, characterization and validation of the PMCB and documenting storage, dispensing and periodic testing of Product Master Cell Bank confirming its integrity and stability, that are owned or Controlled by Seller or its Affiliates.

“Product Net Sales” shall mean the gross amount invoiced by Purchaser or its Affiliates for Product sales, less: (i) reasonable and customary cash discounts consistent with the Seller’s past practices, (ii) customary rebates and Chargebacks, consistent with the Seller’s past practices and (iii) sales credits, refunds, returns and allowances accrued by Purchaser in accordance with GAAP. Such amounts shall be determined from books and records maintained by Purchaser in accordance with GAAP, consistently applied. To the extent that any accrual contemplated by the foregoing clause (iii) is subsequently adjusted in accordance with GAAP, Purchaser shall notify Seller thereof in writing and the Earnout owing hereunder in respect of the Product Net Sales corresponding to such accrued amounts shall be adjusted accordingly and the next subsequent Earnout payment hereunder shall be increased or decreased accordingly.

“Product Patents” shall mean any and all Patent Rights that are Controlled by Seller and/or any of its Affiliates and that relate primarily to the Product and/or the Product Business, as identified on Schedule 1.1(c), and including, without limitation, the Genentech Patents and the Snitman Patents.

“Product Records” shall mean all files, documents, instruments, papers, books and records Controlled by Seller and/or any of its Affiliates, whether in electronic or tangible form, that relate primarily to the Product, the Product Business and/or the Product Intellectual Property, including, without limitation, any and all pricing lists, customer lists, vendor lists, financial data, research and development files, marketing materials, regulatory files, adverse event reports and files; equipment specifications; analytical specifications and validation reports; Product batch records; bills of material; packaging specifications; approved and rejected vendor lists and audits; Product complaints, clinical studies and all documentation relating thereto; all
documentation associated with the Product Intellectual Property; copies of all filings (and supporting documentation) with Governmental Authorities, including, but not limited to, any and all Product NDAs and BLAs; component and labeling purchasing specifications; packaging and quality control SOPs; stability data, records, charts, reports and applicable SOPs; quality assurance/control data, records, charts, reports, and applicable SOPs; budgets; pricing guidelines; ledgers; journals; Assumed Contracts; Promotional Materials; operating data and plans; sales data; target lists; file histories, file wrappers, correspondence, application documents, registration documents, search reports, documents concerning the prosecution history, enforcement or maintenance of rights, or restrictions on use, with respect to the Product Intellectual Property, whether or not required to be kept or maintained under any Law; but excluding (i) the Excluded Data and Materials and (ii) any items to the extent that any Applicable Law prohibits their transfer.

“Product Returns” shall mean returns of Product by customers.

“Product Trademarks” shall mean any and all Trademarks that are Controlled by Seller and/or any of its Affiliates and that relate solely to the Product and/or the Product Business, as identified on Schedule 1.1(c). “Product Trademarks” shall not include the Seller Marks.

“Product Trade Secrets” shall mean any and all Trade Secrets that are Controlled by Seller and/or any of its Affiliates and that relate primarily to the Product and/or the Product Business.

“Promotional Materials” shall mean any and all physician lists, customer lists, marketing studies, marketing plans and strategies, sales force training materials, market research materials, and all advertising, selling, and promotional materials and other similar information and data, including, without limitation, records of sales and cost data for the twelve (12) months ended April 30, 2012, and as of the day prior to the Closing Date, to the extent the foregoing relate primarily to the Product and/or the Product Business, and to the extent the foregoing are within the Seller’s or its Affiliates’ possession as of the Closing Date.

“Property Taxes” shall have the meaning set forth in Section 8.8(c).

“Purchased Assets” shall mean, collectively, the assets of Seller set forth below:

(i) the Product;
(ii) all Inventory identified on Schedule 1.1(a);
(iii) the Assumed Contracts;
(iv) the Regulatory Approvals identified on Schedule 1.1(b);
(v) the Promotional Materials;
(vi) the Product Records;
(vii) the Product Intellectual Property;
(viii) the Product Master Cell Bank and Product Master Cell Bank Records, which are listed on Schedule 1.1(e); and

(ix) all of Seller’s right, title and interest in and to each and all of the foregoing assets set forth in (i) – (viii), supra, including, without limitation, any and all of Seller’s and its Affiliates’ rights to bring any and all causes of action, either in law or in equity, for past, present or future infringement of any of the Product Intellectual Property.

“Purchase Price” shall have the meaning set forth in Section 2.1(b).

“Purchaser” shall have the meaning set forth in the first paragraph of this Agreement.

“Purchaser Confidential Information” shall have the meaning set forth in Section 10.1(b).

“Purchaser Indemnified Parties” shall have the meaning set forth in Section 9.1(a).

“Purchaser Labeling” shall mean the printed labels, labeling and packaging materials, including printed carton, container labels and package inserts, to be prepared by Purchaser after the Closing Date and bearing Purchaser’s name for, or in connection with, packaging of the Product.

“Quality Agreement” shall mean the Quality Agreement executed by and between Seller and Boehringer-Ingelheim in connection with the execution of the B-I Supply Agreement, which Quality Agreement will be one of the Assumed Contracts to be assigned to Opco as part of the Purchased Assets.

“Regulatory Approvals” shall mean all applications for regulatory approval, including new drug applications, abbreviated new drug applications, new drug submissions, and any comparable applications and submissions, together with any and all supplements or modifications or amendments thereto, whether existing, pending, withdrawn or in draft form, prepared and submitted to any Governmental Authority in the Territory with respect to the Product, along with all supporting files, data, studies and reports relating thereto (in tangible and electronic form) and all technical and other information contained therein.

“Schedules” shall refer to the schedules to this Agreement which are hereby incorporated by reference into this Agreement.

“Seller” shall have the meaning set forth in the first paragraph of this Agreement.

“Seller Bank Account” shall have the meaning set forth in Section 2.1(b)(i).

“Seller Confidential Information” shall have the meaning set forth in Section 10.1(c).

“Seller Disclosure Schedule” shall have the meaning set forth in the first paragraph of Article III.

“Seller Indemnified Parties” shall have the meaning set forth in Section 9.1(b).
“Seller Marks” shall mean all Trademarks Controlled by Seller, other than the Product Trademarks, that are used in connection with the Product Business and the Assumed Liabilities as of the Agreement Date.

“Seller SEC Filing” shall have the meaning set forth in Section 3.13(a).


“Straddle Period” shall have the meaning set forth in Section 8.8(c).

“Taxes” shall mean all federal, state, local, foreign and other income, net income, gross income, gross receipts, sales, use, ad valorem, transfer, capital stock, franchise, profits, license, service, add on or alternative minimum tax, occupancy, withholding, payroll, fringe benefits, employment, employees’ income withholding, foreign or domestic withholding, unemployment, disability, excise, severance, stamp, value added, occupation, premium, property (including, real property and personal property taxes and any assessments, special or otherwise), environmental, windfall profits, customs, duties or other taxes, and any fees, assessments, levies, tariffs or charges of any kind that are in the nature of a tax, together with any interest and any penalties, additions to tax or additional amounts with respect thereto (and “Tax” means any one of the foregoing Taxes).

“Tax Return” shall mean any return, declaration, report or statement required to be filed with a Governmental Authority in respect to any Tax (including any attachments thereto, and any amendment thereof), including any information return, claim for refund, amended return or declaration of estimated Tax.

“Territory” shall mean the United States, Canada and Japan.

“Third Party” shall mean any Person other than Purchaser, Parent, Opco or Seller, or an Affiliate of any of them.

“Third Party Claim” shall mean any Proceeding at law or suit in equity by or against a Third Party as to which indemnification will be sought hereunder.

“Trademarks” shall mean any and all U.S., international or foreign trademarks, service marks, trade names, service names, brand names, product names, trade dress, trade styles, logos, symbols, and other product or service source identifiers and general intangibles of a like nature, together with all goodwill associated with any of the foregoing, along with all applications, registrations, renewals and extensions therefor.

“Trade Secrets” shall mean information, including, without limitation, any formula, program, device, method, technique, and/or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, any Third Party who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.
“Transaction Documents” shall mean this Agreement and the Ancillary Agreements.

“Transfer Taxes” shall have the meaning set forth in Section 8.8(b).

“Transition Services Agreement” shall mean that certain transition services agreement in the form attached hereto as Exhibit C.

“Treasury Regulations” shall mean the income tax regulations issued under the Code.

Section 1.2 Construction.

(a) The words “hereof,” “herein” and “hereunder” and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement.

(b) The captions herein are included for convenience of reference only and shall be ignored in the construction or interpretation hereof. References to Articles, Sections, Exhibits, and Schedules are to Articles, Sections, Exhibits, and Schedules of this Agreement unless otherwise specified.

(c) All Exhibits and Schedules annexed hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein. Any capitalized terms used in any Exhibit or Schedule but not otherwise defined therein, shall have the meaning as defined in this Agreement.

(d) Any singular term in this Agreement shall be deemed to include the plural, and any plural term the singular, and words denoting either gender shall include both genders as the context requires. Where a word or phrase is defined herein, each of its other grammatical forms shall have a corresponding meaning.

(e) Whenever the words “include,” “includes” or “including” are used in this Agreement, they shall be deemed to be followed by the words “without limitation,” whether or not they are in fact followed by those words or words of like import.

(f) The use of the word “or” shall not be exclusive.

(g) A reference to any legislation or to any provision of any legislation shall include any modification, amendment, re-enactment thereof, any legislative provision substituted therefore and all rules, regulations and statutory instruments issued or related to such legislation.

(h) Any rule of construction to the effect that ambiguities are to be resolved against the drafting party shall not be applied in the construction or interpretation of this Agreement. No prior draft of this Agreement nor any course of performance or course of dealing shall be used in the interpretation or construction of this Agreement. No parol evidence shall be introduced in the construction or interpretation of this Agreement unless the ambiguity or uncertainty in issue is plainly discernable from a reading of this Agreement without consideration of any extrinsic evidence.
(i) The Parties agree that any exception or qualification set forth in the Seller Disclosure Schedule with respect to a particular representation or warranty contained herein shall be deemed to be an exception or qualification with respect to other representations and warranties contained in this Agreement to the extent the applicability of the disclosure to each other representation and warranty is reasonably apparent from the text of the disclosure made. Nothing in the Seller Disclosure Schedule is intended to broaden the scope of any representation, warranty or covenant of Seller contained in this Agreement.

ARTICLE II
THE TRANSACTION

Section 2.1 Purchase and Sale of Purchased Assets.

(a) Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, Seller shall sell, assign, transfer, convey and deliver to Purchaser, and Purchaser shall purchase, acquire and accept, all of Seller’s right, title and interest in and to the Purchased Assets, free and clear of all Encumbrances other than Permitted Encumbrances; provided that Opco shall purchase, acquire and accept the Inventory, B-I Supply Agreement and Quality Agreement in lieu of Purchaser.

(b) As consideration for the transactions contemplated hereby (the “Purchase Price”), Purchaser shall make the following payments to Seller:

   (i) Closing Cash Payment. At Closing, Purchaser shall make a cash payment of Fifty Five Million Dollars ($55,000,000) (the “Closing Cash Payment”) by wire transfer of immediately available funds to a bank account in the United States identified by Seller to Purchaser in writing at least two (2) Business Days prior to the Closing Date (the “Seller Bank Account”).

   (ii) Additional Consideration.

      A. Earnout. On each of the one (1) year and two (2) year anniversaries of the Closing, Purchaser shall pay to Seller a cash payment (each an “Earnout” and together, the “Earnouts”) by wire transfer of immediately available funds to the Seller Bank Account or, if applicable, to an alternate bank account in the United States identified by Seller to Purchaser in writing (the “Alternate Seller Bank Account”), within forty-five (45) days following the end of each Annual Period, such amount as calculated pursuant to the formulas set forth below:

         • 12.5% of total Product Net Sales from $0 - $10,000,000; and
         • 7.5% of total Product Net Sales from $10,000,001 - $20,000,000.

Product Net Sales shall be calculated on an Annual Period basis and payments of the foregoing Earnouts will be paid within forty-five (45) days after the end of each three (3) month period within each of the first and second Annual Periods.
(iii) Assumed Liabilities. At the Closing, Purchaser shall assume from Seller, and thereafter pay, perform and discharge when due, the Assumed Liabilities.

(c) The B-I Purchase Orders shall constitute Assumed Contracts, provided, however, Seller shall, at Seller’s expense, pay, perform and discharge on Purchaser’s behalf when due the amounts payable to Boehringer-Ingelheim under the B-I Purchase Orders. If Closing occurs prior to the transfer of title from Boehringer-Ingelheim to Seller of Product under the B-I Purchase Orders, the Parties acknowledge and agree that Purchaser may directly instruct Boehringer-Ingelheim to ship or have shipped the Product under the B-I Purchase Orders to Opco pursuant to the terms of the B-I Supply Agreement. If Closing occurs after the transfer of title from Boehringer-Ingelheim to Seller of Product under the B-I Purchase Orders, Purchaser acknowledges and agrees that such Product shall remain at the United States facilities maintained by CORD Logistics, Inc. where CORD Logistics, Inc. shall continue to store and process the Product under the Distribution Services Agreement between CORD Logistics, Inc. and InterMune Pharmaceuticals Inc., dated January 15, 1999, as amended from time to time, but title to such Product shall be transferred to Opco, without further consideration, at the time of Closing as part of the Purchased Assets.

Section 2.2 Excluded Assets. The Parties acknowledge and agree that Seller is not selling, conveying, transferring, assigning, or delivering, or assigning any rights whatsoever to the Excluded Assets to Purchaser, and Purchaser is not purchasing, taking delivery of or acquiring any rights whatsoever to the Excluded Assets from Seller.

Section 2.3 Assumed Liabilities. Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, Purchaser shall assume and agree to pay, perform or otherwise discharge, in accordance with their respective terms and subject to the respective conditions thereof, only the following Liabilities (collectively, the "Assumed Liabilities"); provided that Opco shall assume any such Liability in lieu of Purchaser with respect to the Inventory, B-I Supply Agreement and Quality Agreement:

(a) Any Liability arising on or after the Closing under any Assumed Contract (other than any Liability arising out of or relating to a breach of such Assumed Contract which occurred prior to the Closing);

(b) Any Liability arising out of the conduct of the Product Business by Purchaser after the Closing, including any Liabilities and obligations arising out of or resulting from product liability claims for the Product but only with respect to Product which is sold by Purchaser after the Closing;

(c) Any Liability arising after the Closing for Taxes imposed with respect to the Product Business or the Purchased Assets that are attributable to the ownership, sale, operation or use of the Product Business or the Purchased Assets following the Closing Date;

(d) Property Taxes and Transfer Taxes to the extent specifically allocated to Purchaser pursuant to Section 8.8; and

(e) Any other Liability specifically set forth on Schedule 2.3(e) hereto.

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(f) For the avoidance of doubt, the Parties acknowledge that in no event shall the provisions of this Section 2.3 be construed to limit Purchaser’s, Parent’s or Opco’s obligations under Article IX.

Section 2.4 Excluded Liabilities.

(a) The Parties hereby acknowledge and agree that, other than the Assumed Liabilities, or as otherwise specifically provided in the Transaction Documents, Purchaser shall not be responsible for, assume, or be obligated to pay, perform or otherwise discharge any Liabilities or obligations of Seller, whether or not related to the Product Business (collectively, the “Excluded Liabilities”), which Excluded Liabilities shall include, but not be limited to, (i) any obligation or Liability of Seller created as a result of this Agreement, (ii) any Liability relating to Product sold prior to the Closing Date, or the operation of the Product Business prior to the Closing Date, (iii) those items set forth on Schedule 2.4(a), and (iv) all liabilities with respect to any Taxes owed by Seller, including any liability of Seller for the Taxes of any other Person under Treasury Regulation Section 1.1502-6 (or any similar provision of state, local or foreign law), as a transferee, or as a result of a Tax sharing of similar agreement, and Taxes otherwise imposed with respect to the Product Business or the Purchased Assets that are attributable to the ownership, sale, operation or use of the Product Business or the Purchased Assets on or prior to the Closing Date. For the avoidance of doubt, the Parties acknowledge that in no event shall the provisions of this Section 2.4 be construed to limit Seller’s obligations under Article IX.

(b) The Parties hereby acknowledge and agree that, other than as provided in the Transaction Documents, Seller shall not be responsible for, assume, or be obligated to pay, perform or otherwise discharge any obligations or liabilities of Purchaser. The Parties acknowledge that in no event shall the foregoing sentence be construed to limit Seller’s obligations under Article IX.

Section 2.5 Closing Date. Unless this Agreement shall have been terminated pursuant to Article VII, the consummation of the transactions contemplated by Section 2.1 (the “Closing”) shall take place at the offices of Latham & Watkins LLP, 140 Scott Drive, Menlo Park, CA 94025 at 10:00 a.m., PDT, and in such other places as are necessary to effect the transactions to be consummated at the Closing, on the fifth (5th) Business Day immediately following the satisfaction or, to the extent permitted, waiver of all of the conditions in Article VII (other than those conditions which by their nature are to be satisfied or, to the extent permitted, waived at the Closing but subject to the satisfaction or, to the extent permitted, waiver of such conditions), or at such other time, date and place as shall be determined by mutual agreement of the Parties (such date of the Closing being herein referred to as the “Closing Date”). The Closing shall be deemed to have become effective as of 12:01 a.m., PDT on the Closing Date.

Section 2.6 Purchaser Obligations. At the Closing, Purchaser shall (i) deliver to Seller the Closing Cash Payment and (ii) execute and deliver to Seller the following:

(a) the Bills of Sale;
(b) the Assignment and Assumption Agreements;
Section 2.7 Seller Obligations. At the Closing, Seller shall execute and deliver to Purchaser, the following:
(a) the Bills of Sale;
(b) the Assignment and Assumption Agreements;
(c) the Transition Services Agreement;
(d) the Patent Assignment Agreement;
(e) the Domain Name Assignment Agreement;
(f) the B-I Supply Agreement, Quality Agreement and waiver and consent of Boehringer-Ingelheim, as described in Section 7.2(e) hereof;
(g) a confirmation receipt reflecting receipt of the Closing Cash Payment;
(h) a certificate from Seller under Treasury Regulations Section 1.1445-2 certifying Seller’s non-foreign status;
(i) the certificate required by Section 7.2(a); and
(j) such other documents and instruments as Purchaser may reasonably request to consummate the transactions described in Section 2.1.

Section 2.8 Allocation of Purchase Price. Seller and Purchaser shall allocate the Purchase Price (and Assumed Liabilities, to the extent properly taken into account under the Code) among the Purchased Assets for tax purposes in accordance with Section 1060 of the Code. A draft allocation schedule shall be prepared by Purchaser and delivered to Seller not later than thirty (30) days after the Closing Date for Seller’s review and comment. Seller and Purchaser shall work in good faith to resolve any disputes relating to the draft allocation schedule (such allocation schedule as finally agreed to by Purchaser and Seller, the “Allocation Schedule”). The Allocation Schedule shall be revised as mutually agreed by Purchaser and Seller to reflect any adjustment to the Purchase Price pursuant to the provisions of this
Agreement. Purchaser and Seller shall file all Tax Returns (including, but not limited to, a Form 8594 (Asset Acquisition Statement under Section 1060 of the Code)) with respect to the transactions contemplated by this Agreement consistently with the Allocation Schedule and any adjustments thereto, unless otherwise required by Applicable Law.

Section 2.9 Assignability and Consents. Notwithstanding anything to the contrary contained in this Agreement, but subject to Section 7.2, if the sale, assignment, transfer, conveyance or delivery or attempted sale, assignment, transfer, conveyance or delivery to Purchaser of any Purchased Assets (i) is prohibited by any Applicable Law or (ii) would require any consents, waivers, approvals or authorizations of a Third Party or Governmental Authority (a “Consent”) and such Consents shall not have been obtained prior to the Closing and an attempted assignment thereof without such Consent would constitute a breach thereof, then in either case, the Closing will proceed without the sale, assignment, transfer, conveyance or delivery of such Purchased Assets and this Agreement shall not constitute an agreement for the sale, assignment, transfer, conveyance or delivery of such Purchased Asset. In the event that the Closing proceeds without the sale, assignment, transfer, conveyance or delivery of any such Purchased Asset, then following the Closing, the Parties shall use their commercially reasonable efforts, and cooperate with each other, to obtain promptly such Consents; provided, however, that Purchaser shall not be required to pay any consideration to obtain any such Consent. Pending receipt of such Consents, the Parties shall cooperate with each other in any mutually agreeable, reasonable and lawful arrangements designed to provide to Purchaser the benefits of and the obligations associated with use of such Purchased Asset that it would have had or been subject to had the asset been conveyed to Purchaser at the Closing. To the extent that Purchaser is provided the benefits pursuant to this Section 2.9 of any Assumed Contract, Purchaser shall (x) perform for the benefit of the other parties thereto the obligations of Seller or any Affiliate of Seller thereunder, which arise after the Closing, and (y) shall satisfy any related Liabilities with respect to such Assumed Contract that, but for the lack of a Consent to assign such obligations or Liabilities to Purchaser, would be Assumed Liabilities. Once Consent for the sale, assignment, transfer, conveyance or delivery of any such Purchased Asset not sold, assigned, transferred, conveyed or delivered at the Closing is obtained or given, Seller shall promptly assign, transfer, convey and deliver such Purchased Asset to Purchaser at no additional cost to Purchaser.

Section 2.10 License Grant. Seller hereby grants Purchaser, on Seller’s behalf and on behalf of any applicable Affiliate, a non-exclusive, royalty-free, sublicensable license, under Know-How Controlled by Seller, to use the IPF Patient Data solely for the treatment and support of patients using the Product; provided that, for the avoidance of doubt, Purchaser shall not use any of the IPF Patient Data to seek regulatory approval of or to commercialize the Product for the treatment of idiopathic pulmonary fibrosis.

ARTICLE III
REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Purchaser as of the date hereof, but subject to such exceptions as are specifically disclosed in the disclosure schedule referencing the appropriate Sections hereof (unless the applicability and relevance of the disclosure to another representation or warranty is readily apparent on the face of such disclosure, in which case such disclosure shall
Section 3.1 Organization and Authority. Seller is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Seller has all necessary corporate power and corporate authority, and has taken all actions necessary, to execute and deliver the Transaction Documents, and the transactions contemplated thereby, and effect the transactions contemplated thereby and has duly authorized the execution, delivery and performance of the Transaction Documents and transactions or documents contemplated thereby by all necessary corporate action. Seller has all corporate power and corporate authority necessary to own its assets and carry on the Product Business as currently being conducted by Seller. The Transaction Documents will be upon the Closing, the valid and legally binding obligations of Seller, enforceable against it in accordance with their terms, subject to applicable bankruptcy moratorium, reorganization, insolvency and similar laws of general application relating to or affecting the rights and remedies of creditors generally and to general equitable principles (regardless of whether in equity or at law).

Section 3.2 Purchased Assets; Title to Purchased Assets.

(a) Except as set forth on Section 3.2 of the Seller Disclosure Schedule, the Purchased Assets collectively constitute all of the properties, rights, titles, interests and other tangible and intangible assets owned by Seller and/or any of its Affiliates and used by Seller and/or any of its Affiliates to conduct the Product Business consistent with past practice.

(b) Seller has good and marketable title to the Purchased Assets owned by Seller free and clear of any Encumbrances, except for the Permitted Encumbrances. Seller has not received any notice of any adverse claims of ownership to the Purchased Assets owned by Seller, and to Seller’s Knowledge, no facts or circumstances exist which would provide a reasonable basis for any such adverse claim of ownership of any of the Purchased Assets owned by Seller. Upon delivery to Purchaser at the Closing of the Bills of Sale, Domain Name Assignment Agreement, Patent Assignment Agreement, and the Assignment and Assumption Agreements, Seller will thereby sell, transfer, convey and assign to Purchaser good and marketable title to the Purchased Assets, free and clear of all Encumbrances other than Permitted Encumbrances, subject to the terms and conditions of this Agreement.

Section 3.3 Consents; Non-Contravention.

(a) Except for the requisite filings under the HSR Act, if any, and the expiration or termination of the waiting period thereunder, and except for all filings and other actions contemplated by the Transaction Documents (including the necessary transfer of filings, notices and approvals required to transfer the Regulatory Approvals from Seller to Purchaser), the execution, delivery and performance by Seller of the Transaction Documents and the consummation by Seller of the transactions contemplated thereby will not require any notice to, filing with, or the consent, approval or authorization of, any Person or Governmental Authority.

(b) Except as set forth on Section 3.7 of the Seller Disclosure Schedule, neither the execution and delivery of the Transaction Documents nor the consummation of the transactions...
Section 3.4 Regulatory Approvals

(a) Section 3.4(a) of the Seller Disclosure Schedule sets forth a complete and correct list of all Regulatory Approvals. Seller has provided to Purchaser complete and correct copies of the Regulatory Approvals or Purchaser has had access to such copies of the Regulatory Approvals.

(b) Seller is in material compliance with all of the Regulatory Approvals listed on Section 3.4(a) of the Seller Disclosure Schedule, and, since the time Seller acquired its rights in the Product, Seller has not received any notification or other communication, written or oral, from any Third Party with respect to any alleged or possible violation with respect to any such Regulatory Approvals, and to Seller’s Knowledge, there are no facts or circumstances that would form a reasonable basis for any such violation.

(c) The Regulatory Approvals are in full force and effect and have been duly and validly issued. The U.S. Regulatory Approval is in good standing, has not been revoked, rescinded, amended or modified, and, to Seller’s Knowledge, no event has occurred or notification or other communication been received by Seller from the FDA or other Governmental Authority, a notified body or any other party that would materially adversely affect or otherwise jeopardize the FDA approval status of the Product. To the Knowledge of Seller, no applications made or other materials submitted by Seller to the FDA or other Governmental Authority or a notified body with respect to the Product contained an untrue statement of material fact when submitted, or omitted to state a material fact when submitted which was required to be stated therein or necessary in order to make the statements contained therein, in light of the circumstances under which they were made, not misleading.

(d) The Regulatory Approval files of Seller have been maintained in accordance with reasonable industry standards. Seller has in its possession or control, or has access to, copies of all the material documentation filed in connection with filings made by Seller for Regulatory Approval of the Product, including the complete regulatory chronology for each Regulatory Approval (if applicable) and Seller will, to the extent any such materials are not delivered pursuant to the terms of this Agreement, upon request of Purchaser make such materials available for review and copying by Purchaser and its representatives.

Section 3.5 Compliance with Laws and Litigation

(a) Except with respect to any matter relating to or arising from Regulatory Approvals (which is addressed in Section 3.4), with respect to the Product, the Product Business,
the Purchased Assets and the Assumed Liabilities, Seller is in material compliance with all Applicable Laws.

(b) Except with respect to routine administrative proceedings conducted with respect to Regulatory Approvals conducted in the Seller’s ordinary and usual course of conduct of the Product Business, there are no Proceedings, including any action or investigation by the U.S. Department of Justice, Office of the Inspector General, or any Governmental Authority, existing, pending, or to the Knowledge of Seller, threatened against or affecting Seller, with respect to the Product, the Product Business, the Purchased Assets or the Assumed Liabilities or with respect to this Agreement or the transactions contemplated hereby, and there are no Proceedings pending in which Seller is the plaintiff or claimant and which relate to the conduct of Seller with respect to the Purchased Assets or the Product Business prior to the Closing Date. Seller is not subject to any Proceedings, nor, to the Knowledge of Seller, are any Proceedings threatened, which, in any such case, that would reasonably be expected to impair or delay its ability to perform its obligations under this Agreement.

Section 3.6 No Material Adverse Change

(a) Except as set forth on Section 3.6 of the Seller Disclosure Schedule, since January 1, 2010, there has been no Material Adverse Effect on the Product Business or the Purchased Assets; (b) there has been no damage or impairment to, or destruction or loss of, the Purchased Assets, that had or would reasonably be expected to have a Material Adverse Effect on the Product Business or the Purchased Assets; (c) there has been no sale, assignment, transfer or Encumbrance of the Purchased Assets outside the ordinary course of business; and (d) there has been no change in the contingent obligations of Seller by way of guaranty, endorsement, indemnity, warranty or otherwise that would reasonably be expected to have a Material Adverse Effect.

(b) Since January 1, 2010, Seller has, consistent with the conduct of the Product Business during the twenty-four (24) months prior to the Agreement Date: (i) continued and conducted the Product Business in Seller’s ordinary and usual course of business, and (ii) maintained its relationships with suppliers, distributors, customers and others having material business relationships with Seller related to the Product Business.

Section 3.7 Assumed Contracts

(a) Section 3.7 of the Seller Disclosure Schedule sets forth a complete and correct list of each of the Assumed Contracts. Except as set forth in Section 3.7 of the Seller Disclosure Schedule, the Assumed Contracts constitute all of the contracts to which Seller or any of its Affiliates is a party or is otherwise bound and that are material to or otherwise relate solely or primarily to the Purchased Assets and/or the Product Business. Seller has delivered to or made available to Purchaser true and complete copies of all such Assumed Contracts and any other contracts or agreements identified on Schedule 1.1(d). All such Assumed Contracts are, as to Seller (and, as to the other parties thereto, to the Knowledge of Seller), legal, valid and binding agreements in full force and effect and enforceable in accordance with their respective terms (subject to applicable bankruptcy moratorium, reorganization, insolvency and similar laws of general application relating to or affecting the rights and remedies of creditors generally and to
general equitable principles (regardless of whether in equity or at law)) and, subject to Section 2.9, may be transferred to the Purchaser pursuant to this Agreement and, as of the Closing Date and subject to the provisions of each such Assumed Contract, will continue in full force and effect in each case without the consent, approval, or act, or the making of any filing with, any other party thereto.

(b) Seller is not in material breach or default, and no event has occurred that with notice or lapse of time would constitute a material breach or default by Seller permitting termination, modification, or acceleration, under any Assumed Contract of the Seller Disclosure Schedule. To the Knowledge of Seller, no other party to any Assumed Contract is in material breach or default under, or has repudiated any material provision of, any Assumed Contract, and no event has occurred and no condition or state or facts currently exists which, with time or the giving of notice, or both, would constitute such a material default or breach by such other party.

Section 3.8 Inventory and Returns.

(a) Section 3.8(a) of the Seller Disclosure Schedule sets forth a complete and correct list of the Inventory as of May 15, 2012, as the same will be revised as of the day prior to the Closing Date. The Inventory has been produced or manufactured in accordance with all Applicable Law and Regulatory Approvals.

(b) Since January 1, 2010, Seller has not (i) materially altered its distribution practices or terms with respect to the Product, or (ii) materially altered its activities and practices with respect to inventory levels of the Product maintained at the wholesale, chain, institutional or retail levels in any material respect.

(c) Section 3.8(c) of the Seller Disclosure Schedule sets forth, on a monthly basis, the returns of the Product for the one year period ended May 15, 2012, as the same will be revised as of the day prior to the Closing Date.

(d) All Inventory included in the Purchased Assets shall be fully paid for, saleable and in good and marketable condition and shall be in compliance with all Laws applicable to its manufacture, labeling and storage.

(e) All Inventory identified on Schedule 1.1(a) shall be provided to Opco without additional consideration.

Section 3.9 Tax Matters.

(a) There are no Encumbrances for Taxes on any of the Purchased Assets other than Permitted Encumbrances (within the meaning of clause (i) of such definition).

(b) Seller has timely filed all Tax Returns that were required to be filed relating to the Product Business or the Purchased Assets and has paid all Taxes shown thereon as owing, except where the failure to file Tax Returns or to pay Taxes would not have a Material Adverse Effect.

(c) Except as disclosed on Schedule 3.9(c), there are pending or ongoing against Seller no federal, state, local or foreign audits, suits, proceedings, claims or administrative
proceedings or, to the Knowledge of Seller, investigations, for Taxes of Seller relating to the Product Business or the Purchased Assets or any Tax Returns of Seller relating to the Product Business or the Purchased Assets that could result in (i) a material Encumbrance on the Purchased Assets or (ii) material Taxes for which the Purchaser Indemnified Parties may be liable.

(d) Seller has not received any written ruling concerning Taxes of Seller with respect to the Product Business or the Purchased Assets from any taxing authority.

(e) Except as disclosed on Schedule 3.9(e), during the three (3) year period ending on the date of this Agreement, no jurisdiction where Seller does not file a Tax Return has made a claim in writing that Seller is required to file a Tax Return relating to the Product Business or the Purchased Assets for such jurisdiction or that any Taxes relating to the Product Business of the Purchased Assets are due as a result of doing any business in such jurisdiction.

Section 3.10 Intellectual Property.

(a) Seller is the owner or licensee of all right, title and interest in and to, or otherwise has the right to use, the Product Intellectual Property, free and clear of any Encumbrance, except for the Permitted Encumbrances; Seller has the full and unrestricted right, power and authority to grant, convey, transfer and assign to Purchaser all of Seller’s (and any of its Affiliates’) right, title and interest in and to the Product Intellectual Property; and Seller’s grant, conveyance, transfer and assignment to Purchaser of all of Seller’s (and any of its Affiliates’) right, title and interest in and to the Product Intellectual Property will not violate or breach any Assumed Contract.

(b) Schedule 1.1(c) sets forth a true and complete list of all Product Intellectual Property, and Schedule 1.1(d) sets forth a true and complete list of all Assumed Contracts through which the Seller (and any of its Affiliates) has obtained rights to any Product Intellectual Property.

(c) None of the Product Patents is involved in any Proceeding (including, but not limited to, any Proceeding challenging the ownership, right to use, validity, enforceability, and/or any allegation of infringement, of any of the Product Patents (and whether under the Hatch Waxman Act, the Biologics Price Competition and Innovation Act, or other applicable Law)). To the Knowledge of Seller, no inequitable conduct (i.e., any conduct that would be in violation of 37 C.F.R. §1.56, or its foreign equivalent, if applicable) was committed in the prosecution of any of the Product Patents owned by Seller.

(d) Except as set forth in Section 3.10 of the Seller Disclosure Schedule, to the Knowledge of Seller, none of the Product Trademarks, Product Copyrights or Product Domains is involved in any Proceeding.

(e) To the Knowledge of Seller, all maintenance fees, annuity fees or renewal fee payments have been timely paid, as and if applicable, for each of the Product Patents, Product Trademarks, Product Copyrights and Product Domain Names owned by the Seller.
(f) There are no pending or, to the Knowledge of Seller, threatened Proceedings (i) based upon, challenging, or seeking to deny or restrict, the Seller’s (or, as applicable, any of its Affiliates’) use of any of the Product Intellectual Property, and/or (ii) alleging that the manufacture, use, sale, offer for sale, import, or export of the Product by Seller (or, as applicable, by any of its Affiliates), or the operation of the Product Business, infringes the rights of any Third Party in and to any Intellectual Property.

(g) To the Knowledge of Seller, no Third Party is engaging in any activity that infringes or misappropriates the Product Intellectual Property. Neither Seller nor its Affiliates has received any notice from any Third Party, under either the Hatch Waxman Act or the Biologics Price Competition and Innovation Act, asserting any position of non-infringement, invalidity or unenforceability of any of the Product Patents.

(h) Seller has taken all action reasonable and commensurate with industry best practices: (i) to protect, preserve and maintain the secrecy, confidentiality and value of the Product Trade Secrets and the Product Know-How, and thus, to the Knowledge of Seller, the Product Trade Secrets and/or Product Know-How are not part of the public knowledge or literature, and have not been used, divulged or appropriated either for the benefit of any Third Party or to the detriment of Seller; and (ii) to vest in Seller all right, title, and interest in and to any and all Product Intellectual Property conceived, created or developed by all former and current employees and contractors of Seller or its Affiliates, and thus, to the Knowledge of Seller, no former or current employees and/or contractors of Seller or its Affiliates own, hold or possess, in their individual or any other capacities, any right, title or interest in and to any of the Product Intellectual Property. Any executed agreements obtained by Seller in connection with Seller’s actions under Sections 3.10(h)(i) and (ii), shall be retained by Seller for a period of ten (10) years following the Closing Date, unless Seller gives Purchaser notice of its intention to destroy any such executed agreements and affords Purchaser a reasonable opportunity to take possession or make copies thereof.

(i) Neither Seller nor any of its Affiliates has licensed, granted, conveyed, transferred or assigned to any Third Party any right, title or interest in and to the Product, any of the Product Intellectual Property and/or the Product Business.

Section 3.11 Product Records. All Product Records have been made available by Seller to Purchaser for examination and copying, and all Product Records are complete and correct in all material respects and have been maintained in accordance with reasonable industry standards.

Section 3.12 Brokers, Finders, etc. Other than Locust Walk Partners, whose fees, commission and expenses are the sole responsibility of Seller, Seller has not employed any broker, finder, consultant or other intermediary in connection with the transactions contemplated by the Transaction Documents who would have a valid claim for a fee or commission from Purchaser in connection with such transactions by reason of any action taken by or on behalf of Seller.
Section 3.13 Financial Statements.

(a) Each form, report, schedule and document required to be filed by Seller under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) since January 1, 2010 (collectively, the “Seller SEC Filings” and individually, a “Seller SEC Filing”), solely with respect to the Product Business,
(i) did, as of its date, comply in all material respects with the requirements of the Exchange Act and (ii) did not, at the time it was filed, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading.

(b) Each of the consolidated financial statements (including in each case, any notes thereto) contained in any Seller SEC Filing, solely to the extent each relates to the Product Business, (i) was prepared in accordance with GAAP applied (except as may be indicated in the notes thereto and, in the case of unaudited quarterly financial statements, as permitted by Form 10-Q under the Exchange Act) on a consistent basis throughout the periods indicated, and (ii) presented fairly the consolidated financial position, results of operations and cash flows of Seller as of the respective dates thereof and for the respective periods indicated therein (subject, in the case of unaudited statements, to normal and recurring year-end adjustments which did not result in a Material Adverse Effect).

(c) Seller has previously furnished to Purchaser or has identified to Purchaser and provided Purchaser an opportunity to confirm or review, (i) (A) sales of the Product for the three-year period ended December 31, 2011, (B) representative returns and allowances pertaining to the Product for the three-year period ended December 31, 2011, (C) gross and net sales data and cost of goods to Seller for the three-year period ended December 31, 2011 (collectively, the “Financial Data”). The summary of the Financial Data delivered to Purchaser under the file named PASO Finance Template (Q1 2012).xlsx, a copy of which is attached as Section 3.13(c) of the Seller Disclosure Schedule, was prepared by Seller in good faith from the Product Records, and fairly present, in all material respects, the financial condition and results of operations of the Product Business as of the date thereof and for the periods shown. To the Knowledge of Seller, the Financial Data furnished by Seller to Purchaser does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the facts disclosed therein not materially misleading in light of the circumstances in which disclosed.

Section 3.14 Insurance. There are no material claims currently made against any of the insurance policies of Seller relating to the Product, the Product Business, no material impairment of the amounts of coverage required thereunder, and Seller has no Knowledge of any reasonable basis for any such claims.

Section 3.15 Regulatory Compliance. To the extent applicable to the Product in the Territory:

(a) To the Knowledge of Seller, the Product has been developed, labeled, stored, tested and distributed in compliance with all applicable requirements under the Federal Food Drug and Cosmetic Act 21 U.S.C. §§301 et. seq., its implementing regulations, and all similar Applicable Laws, including those relating to investigational use, premmarket clearance and
applications or abbreviated applications to market a new product, except for noncompliance which individually or in the aggregate would not reasonably be expected to have a Material Adverse Effect.

(b) To the Knowledge of Seller, all pre-clinical and clinical investigations conducted by or on behalf of Seller with respect to the Product have been, and are being, conducted in compliance with all applicable recommendations, policy, and guidance issued by the FDA, 21 C.F.R. Parts 50, 54, 56, 58 and 312 and all other Applicable Laws, including those with respect to good laboratory practices, investigational new drug requirements, good clinical practice requirements (including informed consent and institutional review boards designed to ensure the protection of the rights and welfare of human subjects), and federal and state laws restricting the use and disclosure of protected health information, including but not limited to Health Information Technology for Economic and Clinical Health ("HITECH"), the Health Institute Portability and Accountability Act ("HIPAA"), and regulations related to HITECH and HIPAA, except for noncompliance which individually or in the aggregate would not reasonably be expected to have a Material Adverse Effect.

(c) To the Knowledge of Seller, with respect to the Product (i) all manufacturing operations conducted for the benefit of Seller have been and are being conducted in compliance with the FDA’s current Good Manufacturing Practice regulations for drug products, including 21 C.F.R. Parts 210 and 211, and all similar Applicable Laws, except for noncompliance which, individually or in the aggregate, would not have, or be reasonably likely to have, a Material Adverse Effect; and (ii) Seller is in compliance with all registration and listing requirements set forth in 21 U.S.C. §360 and 21 C.F.R. Part 207, and all similar Applicable Laws, except for noncompliance which individually or in the aggregate would not reasonably be expected to have a Material Adverse Effect.

(d) Since the date of acquisition of the Product (or rights thereto) by Seller, the Product has not been recalled, suspended or discontinued as a result of any action by the FDA or any other foreign Governmental Authority within the Territory, by Seller or by any licensee, distributor or marketer of the Product, within the Territory, or, to the Knowledge of Seller, outside of the Territory.

(e) Seller has not received any notice or other communication from the FDA or any other Governmental Authority alleging any violation of any Law applicable to any activity relating to the Product Business that is subject to the jurisdiction of FDA or any other Governmental Authority, nor has any Governmental Authority commenced, or threatened to initiate, any action to enjoin or place restrictions on the production of the Product.

(f) To the Knowledge of Seller, there are no facts, circumstances or conditions that would be sufficient to presently, or solely with the passage of time in the ordinary course of business, provide a reasonable basis for a recall, suspension or discontinuance of the Product.

(g) Seller is in compliance with 21 U.S.C. §355, 42 U.S.C. §262 and applicable FDA implementing regulations, including 21 C.F.R. Parts 312, 314, 600 and 601 and all similar Applicable Laws, and all terms and conditions of the applicable new drug application, biologic license application and investigational new drug exemption submission under 21 U.S.C. §355(i),
except for any such failure or failures to be in compliance which individually or in the aggregate has not had and would not reasonably be expected to have a Material Adverse Effect. As to the Product, Seller and its officers, employees or agents have included in each applicable application, where required, the certification described in 21 U.S.C. §335a(k)(l) and each such certification was true, complete and correct in all material respects when made.

(h) With respect of the Product or of the Product Business, Seller has not committed any act, made any statement or failed to make any statement that would reasonably be expected to provide a basis for the FDA to invoke its policy respecting “Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities” set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto, or any similar policy. Neither the Seller nor any of its officers, employees or agents has been convicted of any crime or engaged in any conduct with respect to the Product Business for which debarment is mandated by 21 U.S.C. §335a(a) or any similar Law or authorized by 21 U.S.C. §335a(b) or any similar Law.

(i) Seller has delivered to Purchaser or made available to Purchaser copies of all annual safety update reports prepared by Seller with respect to the Product.

Section 3.16 No Other Warranties. Except as expressly provided in the Transaction Documents, Seller does not make any representation or warranty about the Product, the Purchased Assets or the Assumed Liabilities or the Product Business, whatsoever. WITHOUT LIMITING THE FOREGOING, PURCHASER ACKNOWLEDGES THAT, EXCEPT AS EXPRESSLY PROVIDED IN THE TRANSACTION DOCUMENTS, (A) THE PURCHASED ASSETS ARE BEING TRANSFERRED “AS IS,” (B) SELLER MAKES NO REPRESENTATION OR WARRANTY OF ANY KIND OR AS BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND (C) SELLER SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED OR STATUTORY WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY, WARRANT OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF NONINFRINGEMENT.

ARTICLE IV
REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser, Parent and Opco, jointly and severally, hereby represent and warrant to Seller as follows.

Section 4.1 Organization and Authority. Purchaser is a company incorporated under the laws of Ireland. Parent is a limited liability company duly organized, validly existing and in good standing under the laws of Delaware. Opco is a company incorporated under the laws of Ireland. Each of Purchaser, Parent and Opco has all requisite corporate or limited liability company, as applicable, power and authority to execute and deliver the Transaction Documents, and the transactions contemplated thereby, and effect the transactions contemplated thereby and has duly authorized the execution, delivery and performance of the Transaction Documents and transactions or documents contemplated thereby by all necessary corporate or limited liability company, as applicable, action. Each of Purchaser, Parent and Opco has all requisite corporate or limited liability company, as applicable, power and authority necessary to carry on its business as is currently being conducted. The Transaction Documents will be upon
the Closing, the valid and legally binding obligations of each of Purchaser, Parent and Opco, enforceable against them in accordance with their terms, subject to applicable bankruptcy moratorium, reorganization, insolvency and similar laws of general application relating to or affecting the rights and remedies of creditors generally and to general equitable principles (regardless of whether in equity or at law).

Section 4.2 Consents; No Violations.

(a) Except for the requisite filings under the HSR Act, if any, and the expiration or termination of the waiting period thereunder, and except for all filings and other actions contemplated by the Transaction Documents (including the necessary transfer of filings, notices and approvals required to transfer the Regulatory Approvals from Seller to Purchaser), the execution, delivery and performance by each of Purchaser, Parent and Opco of the Transaction Documents and the consummation by Purchaser, Parent and Opco of the transactions contemplated thereby will not require any notice to, filing with, or the consent, approval or authorization of, any Person or Governmental Authority.

(b) Neither the execution and delivery of the Transaction Documents nor the consummation of the transactions contemplated thereby will (i) violate or result in a breach or result in the acceleration or termination of, or the creation in any Third Party of the right to accelerate, terminate, modify or cancel, any indenture, contract, lease, sublease, loan agreement, note or other obligation or liability to which Purchaser, Parent or Opco is a party or is bound, (ii) conflict with, violate or result in a breach of any provision of the organizational documents of Purchaser, Parent or Opco, or (iii) conflict with or violate in any material respect Applicable Law.

Section 4.3 Brokers, Finders, etc. Purchaser, Parent, Opco and their respective Affiliates have not employed any broker, finder, consultant or other intermediary in connection with the transactions contemplated by this Agreement and the Ancillary Agreements who would have a valid claim for a fee or commission from Seller in connection with such transactions by reason of any action taken by or on behalf of Purchaser, Parent or Opco.

Section 4.4 Financing. Purchaser and Parent will collectively have funds sufficient to pay (i) the Closing Cash Payment on the Closing Date and (iii) the Earnouts, if and when applicable.

Section 4.5 Litigation. There are no lawsuits, claims or any civil, administrative or criminal actions, suits, or proceedings or governmental investigations existing, pending, or to the Knowledge of Purchaser, threatened, with respect to this Agreement or the transactions contemplated hereby. None of Purchaser, Parent or Opco is subject to any decree or order of any Governmental Authority that would impair or delay its ability to perform its obligations under this Agreement or the Ancillary Agreements.
ARTICLE V
COVENANTS OF SELLER PRIOR TO CLOSING

Section 5.1 Conduct of the Product Business Prior to Closing.
(a) Subject to Applicable Law or as contemplated by this Agreement or consented to in writing by the Purchaser, Seller shall, consistent with its conduct of the Product Business during the twelve (12) months prior to the Agreement Date: (i) continue and conduct the Product Business in Seller's ordinary and usual course of business, (ii) preserve intact the market for the Product and the goodwill associated with the Product and the Product Intellectual Property, (iii) preserve in full force and effect, and, other than in the ordinary course of business, not amend or alter, any material Contracts and/or any Assumed Contract, (iv) alter its marketing practices in respect of the Product in a manner intended to increase sales of Product prior to Closing, including the offering of incentives which are inconsistent with past practices, (v) sell the Product only in the ordinary course of business and at levels consistent with past practices for comparable periods of time and (vi) continue to maintain its relationships with suppliers, distributors, customers and others having material business relationships with it related to the Product Business.

(b) Between the Agreement Date and the Closing, Seller shall not take any affirmative action which would reasonably be expected to (i) cause Seller to violate Section 5.1(a), or (ii) have a Material Adverse Effect on the Product Business, or with, respect to (i) or (ii), refrain from taking any action which would be reasonably be expected to prevent such an event.

Section 5.2 Notice of Default. Between the Agreement Date and the Closing, Seller shall promptly notify Purchaser in writing if Seller becomes aware of any fact or condition that constitutes a breach of a representation, warranty or covenant of Seller under this Agreement. Any such notice or disclosure shall not be deemed to amend or supplement Seller's disclosure under Article III or any schedule hereto, or to correct or cure any misrepresentation, breach of warranty or breach of covenant.

Section 5.3 No Negotiation. Seller shall not, and shall direct its representatives not to, directly or indirectly, initiate, solicit or knowingly encourage any Acquisition Proposal, or furnish any information to any other Person with respect to, or agree to or otherwise enter into, any Acquisition Proposal. Seller shall promptly notify Purchaser after receipt of any Acquisition Proposal or any request for information relating to the Purchased Assets or the Product Business by any Person who has informed Seller or any of its representatives that such Person is considering making, or has made, an Acquisition Proposal (which notice shall identify the Person making, or considering making, such Acquisition Proposal and shall set forth the material terms of any Acquisition Proposal received), and Seller shall keep Purchaser informed in reasonable detail of the terms, status and other pertinent details of any such Acquisition Proposal or request. Seller shall, and shall direct its representatives to, discontinue any solicitation efforts or negotiations with respect to or in furtherance of any Acquisition Proposal.

Section 5.4 Commercially Reasonable Efforts. Seller shall use commercially reasonable efforts to cause the conditions in Section 7.1 and 7.2 to be satisfied.
Section 5.5 Notice of Government Investigations. Between the Agreement Date and the Closing, Seller shall promptly notify Purchaser in writing if Seller has received any notice from the U.S. Department of Justice, the Office of the Inspector General or any other Governmental Authority that such Governmental Authority has commenced, threatened or intends to commence any action or investigation with respect to the Product Business.

ARTICLE VI
COVENANTS OF PURCHASER AND PARENT PRIOR TO CLOSING

Section 6.1 Notice of Default. Between the Agreement Date and the Closing, Purchaser, Parent and Opco shall promptly notify Seller in writing if Purchaser, Parent or Opco becomes aware of any fact or condition that constitutes a breach of a representation, warranty or covenant of Purchaser, Parent or Opco under this Agreement. Any such notice or disclosure shall not be deemed to amend or supplement Purchaser’s, Parent’s or Opco’s disclosure under Article IV or any schedule hereto, or to correct or cure any misrepresentation, breach of warranty or breach of covenant.

Section 6.2 Commercially Reasonable Efforts. Purchaser, Parent and Opco shall use commercially reasonable efforts to cause the conditions in Section 7.1 and 7.3 to be satisfied.

ARTICLE VII
CLOSING AND TERMINATION

Section 7.1 Conditions Precedent to Obligations of Parties. The respective obligations of Purchaser, Parent, Opco and Seller to consummate the transactions contemplated by this Agreement on the Closing Date are subject to the satisfaction or waiver at or prior to the Closing Date of the following conditions:

(a) No Injunction, etc. No Governmental Authority of competent jurisdiction shall have enacted, issued, promulgated, enforced or entered any Law which is in effect on the Closing Date which would, and no Proceeding by any Governmental Authority shall have been threatened against any of the Parties or any of the officers or directors of any of them seeking to, prohibit, enjoin or restrain the consummation of the transactions contemplated by this Agreement to occur on the Closing Date or otherwise making such transactions illegal.

(b) Regulatory Authorizations. (i) All material consents of Governmental Authorities shall have been obtained and shall be in full force and effect, and (ii) the waiting period under the HSR Act, if applicable, and other any other applicable Antitrust Regulation shall have expired or been terminated.

Section 7.2 Conditions Precedent to Purchaser’s Obligations. Purchaser’s obligations to consummate the transactions contemplated by the Transaction Documents shall be subject to the fulfillment of each of the following additional conditions, any one or more of which may be waived, at Purchaser’s sole discretion, in writing by the Purchaser:

(a) Representations and Warranties. The representations and warranties of Seller in Article III (i) shall have been accurate in all material respects on the Agreement date and (ii) shall be accurate in all material respects on the Closing Date as if made on the Closing Date
(except to the extent that any such representation or warranty is made as of a specified date, in which case such representation or warranty shall be accurate in all material respects as of such date), and Purchaser shall have received a certificate signed on behalf of Seller by an authorized officer of Seller to such effect.

(b) **Performance.** Seller shall have performed and complied in all material respects with all covenants contained in this Agreement that are required to be performed or complied with by it on or prior to the Closing.

(c) **FDA.** With respect to the Product fermentation failure previously disclosed to the FDA by Seller, the FDA shall have approved in writing the Prior-Approval Supplement filed with the FDA by Seller on March 9, 2012 and as supplemented on May 10, 2012 (a true and complete copy of which shall have been provided to Purchaser) and the release and sale of the Product under the B-I Purchase Orders, and Seller shall have delivered such written approval(s) to Purchaser.

(d) **No Material Adverse Effect.** Since the date of this Agreement, no Material Adverse Effect shall have occurred and be continuing.

(e) **B-I Supply Agreements.** (i) Purchaser, on behalf of itself and Opco, shall have agreed to accept the B-I Supply Agreement, (ii) Boehringer-Ingelheim shall have waived its right to terminate the B-I Supply Agreement upon or following assignment of such agreement to Purchaser and (iii) Boehringer-Ingelheim shall have consented in writing to the assignment of the B-I Supply Agreement and Quality Agreement to Opco, each of Sections 7.2(e)(i)-(iii) in the form attached hereto as Exhibit E.

(f) **Genentech License.** Seller shall have delivered to Purchaser the consent of Genentech Inc. to the assignment of the Genentech License to Purchaser.

(g) **Closing Documents.** Purchaser shall have received the documents set forth in Sections 2.7(a) – (i) and any document reasonably requested by Purchaser pursuant to Section 2.7(f) provided that Purchaser shall have made such request for such document no less than ten (10) days prior to the Closing. Such documents shall have been executed by the parties thereto and shall be in full force and effect.

**Section 7.3 Conditions Precedent to Seller’s Obligations.** Seller’s obligation to consummate the transactions contemplated hereby shall be subject to the fulfillment of each of the following additional conditions, any one or more of which may be waived, at Seller’s sole discretion, in writing by Seller:

(a) **Representations and Warranties.** The representations and warranties of Purchaser, Parent and Opco contained in this Agreement shall have been accurate in all material respects on the date of this Agreement and shall be accurate in all material respects as of the Closing Date as if made on and as of the Closing Date (except to the extent that any such representation or warranty is made as of a specified date, in which case such representation or warranty shall be accurate in all material respects as of such date, except for such inaccuracies that, either individually or in the aggregate, have not had a material adverse effect on Purchaser, Parent or Opco, as applicable, and Seller shall have received a certificate signed on behalf of each of
(b) Performance. Purchaser, Parent and Opco shall each have performed and complied in all material respects with all covenants contained in this Agreement that are required to be performed or complied with by them on or prior to the Closing, and Seller shall have received a certificate signed on behalf of each of Purchaser, Parent and Opco by an authorized officer of Purchaser, Parent and Opco, as applicable, to such effect.

(c) Closing Documents. Purchaser shall have executed and delivered to Seller the documents set forth in Sections 2.6(a) – (g) and any document reasonably requested by Seller pursuant to Section 2.6(h) provided that Seller shall have made such request for such document no less than ten (10) days prior to the Closing, and each such agreement and document shall be in full force and effect.

Section 7.4 Termination. This Agreement may be terminated:

(a) at any time before the Closing Date by mutual written consent of Purchaser, Parent, Opco and Seller; or

(b) by Purchaser, Parent, Opco or Seller, in writing, if the transactions contemplated hereby have not been consummated on or before October 31, 2012 (as such date may be extended pursuant to Section 10.6), provided that such failure is not due to the failure of the Party seeking to terminate this Agreement to comply in all material respects with its obligations under this Agreement, including the failure of the Party seeking to terminate this Agreement to satisfy its closing conditions set forth in this Article VII.

Section 7.5 Procedure and Effect of Termination. Upon termination of this Agreement by Purchaser, Parent, Opco or Seller pursuant to Section 7.4, written notice thereof shall forthwith be given to the other Parties and this Agreement shall terminate and the transactions contemplated hereby shall be abandoned without further action by any of the Parties. Termination of this Agreement shall terminate all outstanding obligations and liabilities between the Parties arising from this Agreement except those described in: (i) this Section 7.5, ARTICLE IX, and Section 10.1; (ii) the Confidentiality Agreement; and (iii) any other provisions of this Agreement which by their nature are intended to survive any such termination.

ARTICLE VIII
CERTAIN OTHER COVENANTS

Section 8.1 Necessary Efforts; No Inconsistent Action.

(a) Subject to the other terms and conditions of this Agreement, including the conditions set forth in Article VII, the Parties shall, and shall cause their respective Affiliates to, use their respective commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary, proper or advisable under Applicable Law to consummate and make effective the transactions contemplated by the Transaction Documents and to use their respective commercially reasonable efforts to cause the conditions to each Party’s obligation to close the transactions contemplated hereby as set forth in Article VII to be
satisfied, including all actions necessary to obtain all Consents and all waivers or terminations of applicable waiting periods required for the satisfaction of the conditions set forth in Section 7.1(b), and all other Consents necessary in connection with the consummation of the transactions contemplated by the Ancillary Agreements; provided, however, that the foregoing provisions of this Section 8.1(a) shall not (i) require any Party to perform, satisfy or discharge any obligations of any other Party under this Agreement or otherwise or (ii) subject to the provisions of Section 2.9, require any Party or its Affiliates to expend any money other than for filing fees or expenses or de minimus costs or expenses or agree to any restrictions in order to obtain any Consents. The Parties shall cooperate fully with each other to the extent necessary in connection with the foregoing.

(b) In connection with the efforts referenced in Section 8.1(a), the Parties shall timely and promptly make all filings which may be required for the satisfaction of the condition set forth in Section 7.1(b) by each of them in connection with the consummation of the transactions contemplated hereby. In furtherance and not in limitation of the foregoing, if required under Applicable Law, each Party shall file, or cause to be filed, Notification and Report Forms under the Hart Scott Rodino Antitrust Improvements Act of 1976, as amended (the “HSR Act”), or any other similar filings under Antitrust Regulations of any other Governmental Authority as promptly as practicable following the date of this Agreement and in any event no later than (i) ten (10) Business Days following the date of this Agreement, in the case of Notification and Report Forms under the HSR Act, and (ii) the time prescribed by Applicable Law in the case of requirements under other applicable Antitrust Regulations to the extent a time is prescribed and, if no time is prescribed, as promptly as reasonably practicable. In addition, the Parties shall, and shall cause their respective Affiliates to, cooperate and use their commercially reasonable efforts and take all actions necessary to (A) respond as promptly as practicable to any requests for information from any Governmental Authority, and to avoid and/or overcome any action, including any legislative, administrative or judicial action, and (B) have vacated, lifted, reversed or overturned any judgment, injunction or other order (whether temporary, preliminary or permanent) that restricts, prevents or prohibits, or could restrict, prevent or prohibit, the consummation of the transactions contemplated by this Agreement; provided, however, that in no event shall Seller or any of its Affiliates be required or expected to retain any of the Purchased Assets in order to comply with its obligations in respect of the foregoing. Each Party shall furnish to the other such necessary information and assistance as the other Party may reasonably request in connection with the preparation of any necessary filings or submissions by it to any Governmental Authority. Except as prohibited or restricted by Applicable Law or any Antitrust Regulations, each Party or its attorneys shall provide the other Party or its attorneys the opportunity to make copies of all correspondence, filings or communications (or memoranda setting forth the substance thereof) between such Party or its representatives, on the one hand, and any Governmental Authority, on the other hand, with respect to the Transaction Documents or the transactions contemplated thereby, subject to redaction as reasonably necessary of documents filed pursuant to Item 4(c) of the Hart Scott Rodino Notification and Report Form. Without in any way limiting the foregoing, the Parties shall consult and cooperate with one another, and consider in good faith the views of one another, in connection with any analyses, appearances, presentations, memoranda, briefs, arguments, opinions and proposals made or submitted by or on behalf of any Party in connection with proceedings under or relating to the HSR Act or any other Antitrust Regulation.
Section 8.2 Public Disclosures. Unless otherwise required by Applicable Law, the rules and regulations of any stock exchange or quotation services on which such Party’s stock is traded or quoted, prior to the Closing Date, no news release or other public announcement pertaining to the transactions contemplated by this Agreement will be made by or on behalf of a Party or its Affiliates without the prior written approval of the other Party (which approval shall not be unreasonably withheld, conditioned or delayed). If in the judgment of any Party such a news release or public announcement is required by Applicable Law or the rules or regulations of any stock exchange on which such Party’s stock is traded, the Party intending to make such release or announcement shall to the extent practicable use commercially reasonable efforts to provide prior written notice to the other Party of the contents of such release or announcement and to allow the other Party reasonable time to comment on such release or announcement in advance of such issuance.

Section 8.3 Product Returns, Rebates and Chargebacks. Product Returns, Commercial Rebates and Chargebacks are to be processed by the Parties in accordance with the provisions of the Transition Services Agreement.

Section 8.4 Transitional Trademark License.

(a) As of the Closing Date and for a period of up to twenty-four months (24) months after the Closing Date, Seller hereby grants to Purchaser (or its Affiliates responsible for operating the Product Business after Closing or any Third Party manufacturers utilized by Purchaser in connection with the Product Business after the Closing Date), and Purchaser hereby accepts, a non-exclusive, non-transferable, non-sublicensable (except with respect to such Third Party manufacturers or Purchaser’s Affiliates), royalty-free, paid-up, license in the Territory under the Seller Marks, for use solely in connection with (i) Purchaser’s sale of the Inventory in the Territory, and (ii) Purchaser’s use of the Promotional Materials existing as of the Closing Date and transferred to Purchaser as part of the Purchased Assets, and (iii) the labeling on the Product manufactured by or on behalf of Purchaser as of and after the Closing; provided, however, that such license is being granted solely for transitional purposes and Purchaser shall therefore, notwithstanding the time period provided for above, use its commercially reasonable efforts to as quickly as is reasonably possible cease its use of the Seller Marks after the Closing, but in no event later than twenty-four (24) months after the Closing Date, or such later date (not to exceed an additional six (6) months) upon consent by Seller, such consent not be unreasonably withheld.

(b) To the extent that Purchaser is utilizing the transitional trademark license set forth in Section 8.4(a), Purchaser shall not (i) add any marks to, or otherwise alter, the Seller Marks as used in the Product Business as of the Closing Date (except as required by Applicable Law); (ii) change in any way the style of the Seller Marks as used in the Product Business as of the Closing Date; or (iii) otherwise use the Seller Marks in any manner other than as specifically provided in this Section 8.4.

(c) Purchaser acknowledges Seller’s ownership of the Seller Marks, shall do nothing inconsistent with such ownership, and agrees not to challenge Seller’s title to the Seller Marks. Nothing in this Agreement shall give Purchaser any right, title or interest in the Seller Marks other than the right to use the Seller Marks strictly in accordance with this Section 8.4. All use
of the Seller Marks by Purchaser under this Section 8.4 shall conform to the standards followed by Seller in operating the Product Business prior to the Closing Date, and Seller shall have the right to review the standards used by Purchaser to operate the Product Business after the Closing Date to ensure Purchaser’s compliance with this requirement related to the Seller Marks.

(d) Purchaser shall not have the right to, and shall not, sublicense, assign, pledge, grant or otherwise encumber or transfer to any Third Party any rights licensed by Seller to Purchaser under Section 8.4(a) without Seller’s prior written consent. The Parties understand and agree that, in addition to all other legal remedies, Seller shall be entitled to immediate injunctive relief in order to enforce the terms of this Section 8.4.

(e) Nothing in this Section 8.4, or any other provision of this Agreement or any provision of the Ancillary Agreements, shall grant the Purchaser any rights in any of Seller’s Internet domain names, registrations or applications for registration, or renewals thereof, registered in the United States or any other country or jurisdiction throughout the world, except as such Internet domain names, registrations or applications for registration, or renewals thereof are included as part of the Purchased Assets.

(f) Following the Closing, Purchaser shall promptly and at its own expense use commercially reasonable efforts to obtain such FDA approvals necessary for Purchaser Labeling for the Product to be manufactured after the Closing and, promptly comply with such FDA approvals upon receipt thereof.

Section 8.5 Customer Billing. In the event that Seller or any of its Affiliates receives payment after the Closing Date on invoices relating to the Product Business operated by the Purchaser or sales of products or services rendered by Purchaser on or after the Closing, Seller will promptly notify Purchaser of such receipt and will promptly remit, or will cause such Affiliate to promptly remit, such payment to Purchaser without depositing such payment in an account of Seller, or such Affiliate, unless in error, and Seller, or such Affiliate, shall not be entitled to offset such payment against any payments due Seller from Purchaser. In the event Seller receives an invoice or request for payment relating to the operation of the Product Business on or after the Closing Date, or with respect to any Assumed Liability, Seller will promptly notify Purchaser of such request or invoice and forward the invoice and all other appropriate information to Purchaser for payment. In the event Purchaser or any of its Affiliates receive payment after the Closing Date on invoices issued by Seller relating to an Excluded Asset (such as Seller’s accounts receivable as of the Closing Date) or relating to product sold or services rendered by businesses other than the Product Business or the Purchased Assets, Purchaser will promptly notify Seller of such receipt and will promptly remit, or will cause such Affiliate to promptly remit, such payment to Seller without depositing such payment in an account of Purchaser, or such Affiliate, unless in error, and Purchaser, or such Affiliate, shall not be entitled to offset such payment against any payments due Purchaser from Seller.

Section 8.6 Cooperation.

(a) After the Agreement Date, the Parties shall cooperate reasonably with each other in connection with any reasonable actions required to be taken with respect to their respective obligations under this Agreement and the Ancillary Agreements, and shall (i) furnish upon
reasonable request to each other such further information, and (ii) execute and deliver to each other such other reasonable documents, and (iii) do such other acts, all as the other Party may reasonably request for the purpose of carrying out the provisions of this Agreement (and the Ancillary Agreements) and the transactions contemplated hereby and thereby.

(b) The Parties will promptly notify each other in writing, of any event or fact which represents a material breach of any of their respective representations, warranties, covenants or agreements hereunder.

Section 8.7 Reserved.

Section 8.8 Tax Matters

(a) Seller and Purchaser shall provide reasonable cooperation and information to each other in connection with (i) the preparation or filing of any Tax Return, Tax election, Tax consent or certification, or any claim for a Tax refund, (ii) any determination of liability for Taxes and (iii) any audit, examination or other proceeding in respect of Taxes related to the Product Business. Seller and Purchaser shall make themselves (and their respective employees) reasonably available on a mutually convenient basis to provide an explanation of any documents or information provided under this Section 8.8(a). Each of Seller and Purchaser shall retain all Tax Returns, work papers and all material records or other documents in its possession (or in the possession of its Affiliates) relating to Tax matters of the Product Business for any taxable period that includes the Closing Date and for all prior taxable periods until the later of (i) the expiration of the statute of limitations of the taxable period to which such Tax Returns and other documents relate, without regard to extensions, or (ii) six (6) years following the due date (without extension) for such Tax Returns. Prior to the expiration of such time, if Seller or Purchaser desire to retain any such documents in the other’s possession (or in the possession of the other party’s Affiliates), such party desiring to retain such document shall give notice to the other party at least ninety (90) days’ prior to the later of (i) the expiration of the statute of limitations of the taxable period to which such Tax Returns and other documents relate, without regard to extensions, or (ii) six (6) years following the due date (without extension) for such Tax Returns, requesting that such other party remove and retain all or any part of the such documents (at such party’s request). Any information obtained under this Section 8.8(a) shall be kept confidential pursuant to Section 10.1, except as may be otherwise necessary in connection with the filing of Tax Returns, claims for a Tax refund or in conducting any audit, examination or other proceeding in respect of Taxes.

(b) Purchaser and Seller shall each be responsible for fifty percent (50%) of all sales, use, transfer, value added and other similar Taxes (the “Transfer Taxes”), if any, arising out of the transfer by Seller of the Purchased Assets to Purchaser pursuant to this Agreement; provided that, Seller shall have no responsibility for, and Purchaser will be solely responsible for, any value added Tax payable in connection with the sale, assignment, transfer, conveyance and delivery to Purchaser of the Inventory identified on Schedule 1.1(a) and the Product under the BI Purchase Orders pursuant to Section 2.1(c).

(c) All real property, personal property and similar ad valorem Taxes (collectively, “Property Taxes”) levied with respect to the Purchased Assets for the Tax period in which the
Closing Date occurs (a “Straddle Period”) shall be apportioned between Purchaser and Seller based on the number of days of such Straddle Period included in the portion of such period ending on the Closing Date (the “Pre-Closing Tax Period”) and the number of days of such Straddle Period included in the portion of such period beginning after the Closing Date (the “Post-Closing Tax Period”). Seller shall be liable for the proportionate amount of such Property Taxes that is attributable to the Pre-Closing Tax Period, and Purchaser shall be liable for the proportionate amount of such Property Taxes that is attributable to the Post-Closing Tax Period. Upon receipt of any bill for such Property Taxes, Purchaser or Seller, as applicable, shall present a statement to the other setting forth the amount of reimbursement to which each is entitled under this Section 8.8(c) together with such supporting evidence as is reasonably necessary to calculate the proration amount. The proration amount shall be paid by the party owing it to the other within ten (10) days after delivery of such statement.

(d) Purchaser and Seller agree and acknowledge that no withholding of Taxes is required under Irish or other Applicable Law with respect to any of the payments contemplated by Section 2.1 and that no payments under Section 2.1 shall be reduced by any withholding Taxes.

Section 8.9 Notice to Customers. Seller agrees to cooperate with Purchaser, at Purchaser’s reasonable request, in the notification to customers of the transactions contemplated by this Agreement and Seller agrees not to notify any customer of such transactions without the consent of Purchaser. Such notification shall be in such form as is reasonably satisfactory to both Purchaser and Seller as agreed to prior to Closing.

Section 8.10 Adverse Experience Reports. At a mutually agreed upon time after the Closing, Seller shall provide Purchaser with information relating to the investigation and reporting of all adverse experiences regarding the Product prior to the Closing and all other information which is materially relevant to the safe use of the Product in Seller’s possession as of the Closing. After the Closing, Seller shall promptly submit to Purchaser all adverse drug experience information or customer complaints brought to the attention of Seller in respect of the Product, as well as any material events and matters concerning or affecting the safety or efficacy of the Product. After the Closing and after the time the appropriate Governmental Authorities are notified of the transfer of the applicable Regulatory Approvals, Purchaser shall have all responsibility for required reporting of adverse experiences for the Product.

Section 8.11 Regulatory Matters.

(a) Except as expressly set forth in Section 8.10 or the Transition Services Agreement, from and after the Closing, Purchaser, at its cost, shall be solely responsible and liable for (i) taking all actions, paying all fees and conducting all communication with the appropriate Governmental Authority required by Applicable Law in respect of the Regulatory Approvals, including preparing and filing all reports (including adverse drug experience reports) with the appropriate Governmental or Regulatory Authority (whether the Product is sold before or after transfer of such Regulatory Approval), (ii) taking all actions and conducting all communication with third parties in respect of the Product sold pursuant to such Regulatory Approval (whether sold before or after transfer of such Regulatory Approval), including responding to all complaints in respect thereof, including complaints related to tampering or
contamination, and (iii) investigating all complaints and adverse drug experiences in respect of the Product sold pursuant to such Regulatory Approval (whether sold before or after transfer of such Regulatory Approval).

(b) From and after the Closing, and subject to Section 8.10 hereof and the Transition Services Agreement, Seller promptly (and in any event within the time periods required by Applicable Law) shall notify Purchaser within three (3) Business Days if Seller receives a complaint or a report of an adverse drug experience in respect of the Product. In addition, Seller shall cooperate with Purchaser’s reasonable requests and use commercially reasonable efforts to assist Purchaser in connection with the investigation of and response to any complaint or adverse drug experience related to the Product sold by Seller.

(c) From and after the Closing, Purchaser, at its cost, shall be solely responsible and liable for conducting all voluntary and involuntary recalls of units of the Product sold pursuant to such Regulatory Approval (whether sold before or after transfer of such Regulatory Approval), including recalls required by any Governmental Authority and recalls of units of the Product sold by Seller deemed necessary by Seller in its reasonable discretion; provided, however, that Seller shall reimburse Purchaser for the reasonable expenses and costs of conducting recalls relating to Product sold by or on behalf of Seller prior to the Closing, including the costs of notifying customers, the costs associated with shipment of such recalled Product, the price paid for such Inventory, and reasonable credits extended to customers in connection with the recall. Seller shall notify Purchaser promptly in the event that a recall of the Product sold by Seller is necessary.

(d) Seller shall, within fifteen (15) days after the Closing, notify the FDA of the transfer of the Regulatory Approvals to Purchaser in accordance with all Applicable Laws.

Section 8.12 Product Records. At the Closing, or as soon as possible thereafter, Seller shall transfer to Purchaser, to the extent in Seller’s actual possession, the original copies of the Product Records and Assumed Contracts. Seller may retain one (1) archival copy of the Product Records and Assumed Contracts solely for archival purposes or as required by Applicable Law. Prior to delivering or making available any Product Records to Purchaser, Seller shall be entitled to redact therefrom any information that does not relate to the Product Business.

Section 8.13 Employees. The Parties acknowledge and agree that there is no intent or agreement that any employee of Seller will terminate his or her employment with Seller and/or commence employment with Purchaser as a result of the transactions contemplated by this Agreement.

Section 8.14 Non-Competition.

(a) Seller hereby covenants and agrees that, for a period of five (5) years from the Closing Date, neither Seller nor any of its Affiliates (either alone or in collaboration with any Third Party) shall (i) make, use, develop, promote, advertise, market, distribute, sell, offer to sell, import, export and/or commercialize the Product and/or any Competing Product, for any use, purpose, indication or treatment (whether for the treatment of idiopathic pulmonary fibrosis, or any other disease or disorder), anywhere in the Territory or elsewhere in the world, (ii) engage in
any aspect of the Product Business, (iii) file any applications for regulatory approval, including new drug applications, abbreviated new drug applications, new drug submissions, and any comparable applications and submissions, with any Governmental Authority in the Territory or elsewhere in the world, with respect to the Product and/or any Competing Product, for any use, purpose, indication or treatment (whether for the treatment of idiopathic pulmonary fibrosis, or any other disease or disorder) and/or (iv) use any of the Excluded Assets or IPF Patient Data to engage in any conduct prohibited under Sections 8.14(a)(i)-(iii), provided that this Section 8.14(a) shall not apply to non-affiliated successors or assigns of Seller.

(b) Purchaser, Parent and Opco hereby covenant and agree that, for a period of five (5) years from the Closing Date, neither Purchaser, Parent, Opco nor any of their respective Affiliates (either alone or in collaboration with any Third Party) shall (i) make, use, develop, promote, advertise, market, distribute, sell, offer to sell, import, export and/or commercialize the Product for the treatment of idiopathic pulmonary fibrosis, anywhere in the Territory or elsewhere in the world, and/or (ii) file any applications for regulatory approval, including new drug applications, abbreviated new drug applications, new drug submissions, and any comparable applications and submission, with any Governmental Authority in the world, with respect to the Product for any use, purpose, indication or treatment (whether for the treatment of idiopathic pulmonary fibrosis, or any other disease or disorder) and/or any of its Affiliates or IPF Patient Data to engage in any conduct prohibited under Sections 8.14(b)(1)-(2); provided that this Section 8.14(b) shall not apply to non-affiliated successors or assigns of Purchaser. Seller hereby covenants and agrees that neither Seller nor any of its Affiliates (either alone or in collaboration with any Third Party) shall prevent, limit, restrict or impair any of Purchaser’s rights set forth in this Section 8.14(b).

(c) Nothing in this Section 8.14 or in the Transaction Documents shall operate or be construed as a waiver, disclaimer, abridgment, abrogation or truncation of any of Purchaser’s, Parent’s, Opco’s and/or any of their respective Affiliates’ rights, titles and/or interests in and to the Product Intellectual Property and/or in and to any Intellectual Property owned or licensed (as licensor or licensee) by Purchaser, Parent, Opco and/or any of their respective Affiliates. For the avoidance of doubt, nothing in this Section 8.14 or in the Transaction Documents shall operate or be construed as assigning, conveying, transferring or granting to Seller and/or any of its Affiliates any rights, titles, interests, licenses or authorities in and to any of the Product.
Section 8.14 Seller’s Additional Covenants and Agreements.

(a) Seller hereby covenants and agrees that neither Seller nor any of its Affiliates (either alone or in collaboration with any Third Party) shall, at any
time on or subsequent to the Closing Date, challenge or otherwise contest before any Governmental Authority or via any Proceeding (i) Purchaser’s right, title
and interest in and to the Product, the Product Business, and the Product Intellectual Property, (ii) the validity and/or the enforceability of any of the Product
Intellectual Property, (iii) Purchaser’s right to seek and obtain any copyright, patent and/or trademark protection for the Product, the Product Business, and/or
any of the Product Intellectual Property, (iv) the validity and/or the enforceability of any copyright(s), patent(s) and/or trademark(s) so obtained by Purchaser
for the Product, the Product Business, and/or any of the Product Intellectual Property, (v) Purchaser’s right to retain any and all income, revenue, profit,
royalties, damages, claims and payments attributable thereto, payable in connection therewith, or otherwise derived therefrom, without any duty to account
to Seller (excepted as otherwise provided under this Agreement), (vi) Purchaser’s right to bring any and all causes of action, either in law or in equity, for past,
present or future infringement of any of the Product Intellectual Property, (vii) Purchaser’s right to exploit the Product Intellectual Property for whatever
purposes Purchaser shall elect to pursue, including, without limitation, improvements, combinations and analogies thereof and commercialization for new
uses and indications (other than for the treatment of idiopathic pulmonary fibrosis) or as otherwise restricted by the terms of this Agreement, and
(viii) Purchaser’s right to any and all rights, titles and interests corresponding to the foregoing throughout the world.

(b) Seller hereby covenants and agrees that neither Seller nor any of its Affiliates (either alone or in collaboration with any Third Party) shall, at any
time on or subsequent to the Closing Date (i) undertake any action that may damage, diminish, impair or infringe upon, any of Purchaser’s right, title and/or
interest in and to the Product, the Product Business, and/or any of the Product Intellectual Property, (ii) assist any Third Party in challenging or otherwise
contesting Purchaser’s rights, titles and interests in and to the Product, the Product Business and/or any of the Product Intellectual Property, anywhere in the
world, (iii) use any of the Product Intellectual Property, and/or (iv) obtain or assert any right(s), title(s) or interest(s) to any patent, trademark or copyright
relating to the Product, the Product Business and/or any of the Product Intellectual Property.

(c) To the extent that Seller, at the time of Closing, has any right, title or interest in Intellectual Property which, subsequent to Closing, Seller
reasonably determines would materially prevent, limit, restrict or impair Purchaser’s ability to (i) commercialize the Product, (ii) engage in the Product
Business, (iii) exercise or exploit any of the Product Intellectual
Property, and/or (iv) bring any and all causes of action, either in law or in equity, for past, present or future infringement of any of the Product Intellectual Property, (the “Additional Intellectual Property”), the Seller shall notify Purchaser of such determination and the Parties will work in good faith to provide Purchaser with the rights to such Additional Intellectual Property solely in the Product Business.

ARTICLE IX
INDEMNIFICATION

Section 9.1 Indemnification.

(a) Subject to the terms and conditions of this Article IX, from and after the Closing, Seller shall indemnify, reimburse, defend and hold harmless Purchaser, its Affiliates and their respective officers, directors, managers, employees, stockholders, members, agents, successors and assigns (collectively, the “Purchaser Indemnified Parties”) from and against, and shall compensate and reimburse each Purchaser Indemnified Party, for any and all Losses incurred by such Purchaser Indemnified Party to the extent arising or resulting from:

(i) any inaccuracy or breach of any representation or warranty of Seller contained in this Agreement;
(ii) any breach of any covenant or agreement of Seller contained in this Agreement or in any of the Ancillary Agreements; or
(iii) the failure of Seller or any of its Affiliates to pay, perform or discharge any Excluded Liabilities; or
(iv) any Third Party claim by a Third Party relating to the conduct of the Product Business by Seller or any of its Affiliates prior to the Closing.

(b) Subject to the terms and conditions of this Article IX, from and after the Closing, Purchaser, Parent and Opco shall, jointly and severally, indemnify, reimburse, defend and hold harmless Seller, its Affiliates and their respective officers, directors, managers, employees, stockholders, agents, successors and assigns (collectively, the “Seller Indemnified Parties”) from and against, and shall compensate and reimburse each Seller Indemnified Party for, any and all Losses incurred by such Seller Indemnified Party to the extent arising or resulting from:

(i) any inaccuracy or breach of any representation or warranty of Purchaser, Parent or Opco contained in this Agreement;
(ii) any breach of any covenant or agreement of Purchaser, Parent or Opco contained in this Agreement or in any of the Ancillary Agreements;
(iii) the failure of Purchaser or any of its Affiliates to pay, perform or discharge any Assumed Liabilities; or
(iv) any Third Party Claim by a Third Party relating to the conduct of the Product Business by Purchaser or any of its Affiliates from and after the Closing.

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Closing, except to the extent such Third Party Claim arises directly out of (1) any inaccuracy or breach of any representation or warranty of Seller contained in this Agreement or in any of the Ancillary Agreements, or (2) the negligence, recklessness, bad faith, or intentional wrongful acts or omissions of Seller or its Affiliates.

(c) NOTWITHSTANDING THE FOREGOING, PURCHASER LOSSES AND SELLER LOSSES SHALL NOT INCLUDE, AND IN NO EVENT SHALL ANY PURCHASER LOSSES OR SELLER LOSSES BE RECOVERABLE UNDER THE TERMS OF THIS AGREEMENT TO THE EXTENT SUCH DAMAGES CONSIST OF PUNITIVE, SPECIAL OR EXEMPLARY DAMAGES, EXCEPT TO THE EXTENT SUCH PUNITIVE, SPECIAL OR EXEMPLARY DAMAGES ARE AWARDED AGAINST ANY PURCHASER INDEMNIFIED PARTY OR SELLER INDEMNIFIED PARTY, AS THE CASE MAY BE, IN A THIRD-PARTY CLAIM.

Section 9.2 Certain Limitations. Notwithstanding anything to the contrary contained in this Agreement, each of the following limitations shall apply:

(a) Seller will not be required to indemnify Purchaser under Sections 9.1(a)(i) (other than Losses incurred as a result of any inaccuracy or breach of any representation or warranty contained in Sections 3.1 (Organization and Authority), 3.2(b) (Title to Purchased Assets), 3.9 (Tax Matters), 3.12 (Brokers, Finders, etc.), or attributable to fraud or intentional misconduct, as to which this Section 9.2(a) shall not apply), except to the extent that the cumulative amount of the Losses under Section 9.1(a)(i) incurred by the Purchaser Indemnified Parties exceeds Two Hundred Fifty Thousand Dollars (U.S. $250,000) (the “Basket Amount”) at which point Seller will be required to pay, and will have Liability for, the cumulative amount of the Losses under Section 9.1(a)(i) incurred by the Purchaser Indemnified Parties.

(b) Purchaser, Parent and Opco will not be required to indemnify Seller under Section 9.1(b)(i) (other than Losses incurred as a result of any inaccuracy or breach of any representation or warranty contained in Sections 4.1 (Organization and Authority) or 4.3 (Brokers, Finders, etc.), or attributable to fraud or intentional misconduct, as to which this Section 9.2(b) shall not apply) except to the extent that the cumulative amount of the Losses under Section 9.1(b)(i) incurred by the Seller Indemnified Parties exceeds the Basket Amount at which point Purchaser, Parent and Opco, jointly and severally, will be required to pay, and will have Liability for, the cumulative amount of the Losses under Section 9.1(b)(i) incurred by the Seller Indemnified Parties.

(c) In no event shall the aggregate out-of-pocket Liability of Seller for any Losses pursuant to Sections 9.1(a)(i) exceed Five Million Five Hundred Thousand Dollars (U.S. $5,500,000) (the “Cap”); provided, that Losses incurred as a result of any inaccuracy or breach of any representation or warranty contained in Section 3.1 (Organization and Authority), 3.2(b) (Title to Purchased Assets), 3.9 (Tax Matters) and 3.12 (Brokers, Finders, etc.) shall not exceed the Purchase Price; provided, further, that the limitations set forth in this Section 9.2(c) shall not apply to Losses attributable to fraud or intentional misconduct.
(d) In no event shall the aggregate out-of-pocket Liability of Purchaser, Parent or Opco for any Losses pursuant to Sections 9.1(b)(i) (other than Losses incurred as a result of any inaccuracy or breach of any representation or warranty contained in or attributable to fraud or intentional misconduct, as to which this Section 9.2(d) shall not apply) exceed the Cap; provided, that Losses incurred as a result of any inaccuracy or breach of any representation or warranty contained in Sections 4.1 (Organization and Authority) or 4.3 (Brokers, Finders, etc.) shall not exceed the Purchase Price; provided, further, that the limitations set forth in this Section 9.2(d) shall not apply to Losses attributable to fraud or intentional misconduct.

(e) In no event shall Seller, Purchaser, Parent or Opco have any Liability under Section 9.1(a)(i), or 9.2(b)(i), as the case may be, with respect to claims that are not properly asserted in writing prior to the date that is eighteen (18) months after the Closing Date (other than claims for Losses incurred as a result of any inaccuracy or breach of any representation or warranty attributable to fraud or intentional misconduct, as to which this Section 9.2(e) shall not apply); provided, however, that (i) claims for Losses incurred as a result of any inaccuracy or breach of any representation or warranty contained in Sections 3.1 (Organization and Authority), 3.2(b) (Title to Purchased Assets), 3.9 (Tax Matters), 3.12 (Brokers, Finders, etc.), 4.1 (Organization and Authority) or 4.3 (Brokers, Finders, etc.), may be asserted at any time prior to expiration of the applicable statute of limitations and (ii) claims attributable to fraud or intentional misconduct, will have no expiration date.

(f) The representations and warranties made by each Party in this Agreement shall survive the Closing and shall expire eighteen (18) months after the Closing Date and any Liability of any Party with respect to such representations and warranties (other than Losses incurred as a result of any inaccuracy or breach of any representation or warranty contained in (i) Sections 3.1 (Organization and Authority), 3.2(b) (Title to Purchased Assets), 3.9 (Tax Matters), 3.12 (Brokers, Finders, etc.), 4.1 (Organization and Authority) and 4.3 (Brokers, Finders, etc.), which shall expire upon expiration of the applicable statute of limitations, or (ii) attributable to fraud or intentional misrepresentation, as to which no expiration date shall apply; provided, however, that if, at any time prior to such expiration date, notice of any case for indemnification pursuant to Section 9.1(a) or Section 9.1(b), as the case may be, shall have been given prior to the applicable expiration date and such notice describes the circumstances with respect to which such indemnification claim relates, such indemnification claim shall survive until such time as such claim is finally resolved.

Section 9.3 Procedures for Third Party Claims and Excluded Liabilities

(a) General Procedures. Promptly (but in no event later than ten (10) days) after the receipt by any Indemnified Party of a notice of any Proceeding by any Third Party that may be subject to indemnification under this Article IX, including any Proceeding relating to any Excluded Liability or Assumed Liability, such Indemnified Party shall give written notice of such Proceeding to the Indemnifying Party, stating in reasonable detail the nature and basis of each claim made in the Proceeding and the amount thereof, to the extent known, along with copies of the relevant documents received by the Indemnified Party evidencing the Proceeding and the basis for indemnification sought. Failure of the Indemnified Party to give such notice shall not relieve the Indemnifying Party from liability on account of this indemnification, except if and only to the extent that the Indemnifying Party is actually prejudiced thereby. Thereafter,
the Indemnified Party shall deliver to the Indemnifying Party, promptly after the Indemnified Party’s receipt thereof, copies of all notices and documents (including court papers) received by the Indemnified Party relating to the Proceeding. The Indemnifying Party shall have the right to assume the defense of the Indemnified Party against the Third Party Claim upon written notice to the Indemnified Party delivered within thirty (30) days after receipt of the particular notice from the Indemnified Party; provided, however, that the Indemnifying Party shall not have the right to assume the defense of the Third Party Claim if such Third Party Claim (x) seeks as a remedy the imposition of an equitable remedy that is binding upon Purchaser, Parent or Opco, the Purchased Assets or the Assumed Liabilities or (y) the amounts of Losses would be reasonably expected to exceed the amounts for which the Indemnifying Party is obligated to indemnify. So long as the Indemnifying Party has assumed the defense of the Third Party Claim in accordance herewith and notified the Indemnified Party in writing thereof, (i) the Indemnified Party may retain separate co-counsel at its sole cost and expense and participate in the defense of the Third Party Claim, it being understood that the Indemnifying Party shall pay all reasonable costs and expenses of counsel for the Indemnified Party after such time as the Indemnified Party has notified the Indemnifying Party that it has assumed the defense of such Third Party Claim and prior to such time as the Indemnifying Party has notified the Indemnified Party that it has assumed the defense of such Third Party Claim, (ii) the Indemnified Party shall not file any papers or consent to the entry of any judgment or enter into any settlement with respect to the Third Party Claim without the prior written consent of the Indemnifying Party (not to be unreasonably withheld, conditioned or delayed) and (iii) the Indemnifying Party will not consent to the entry of any judgment or enter into any settlement with respect to the Third Party Claim (other than a judgment or settlement that is solely for money damages in an amount less than the remaining balance of the limitations on indemnity set forth in Section 9.2 and is accompanied by a release of all indemnifiable claims against the Indemnified Party) without the prior written consent of the Indemnified Party (not to be unreasonably withheld, conditioned or delayed). Whether or not the Indemnifying Party shall have assumed the defense, such Indemnifying Party shall not be obligated to indemnify and hold harmless the Indemnified Party hereunder for any settlement entered into without the Indemnifying Party’s prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed.

(b) Equitable Remedies. In the case of any Third Party Claims where the Indemnifying Party reasonably believes that it would be appropriate to settle such claim using equitable remedies (i.e., remedies involving the future use of the Purchased Assets), the Indemnifying Party and the Indemnified Party shall work together in good faith to agree to a settlement; provided, however, that no Party shall be under any obligation to agree to any such settlement.

(c) Treatment of Indemnification Payments; Insurance Recoveries. Any payment made pursuant to the indemnification obligations arising under this Agreement shall be treated as an adjustment to the Purchase Price to the extent allowable under Applicable Law. Any indemnity payment under this Agreement shall be decreased by any amounts actually received by the Indemnified Party under Third Party insurance policies with respect to such Damage prior to the time payment by the Indemnifying Party is due and payable under this Agreement (net of any premiums paid by such Indemnified Party under the relevant insurance policy and any costs incurred by such Indemnified Party in procuring such payment under such policy), each Party agreeing (i) to use commercially reasonable efforts to recover all available insurance proceeds
and (ii) to the extent that any indemnity payment under this Agreement has been paid by the Indemnifying Party to or on behalf of the Indemnified Party prior to the receipt, directly or indirectly, by the Indemnified Party of any net insurance proceeds under Third Party insurance policies on account of such Loss which duplicate, in whole or in part, the payment made by the Indemnifying Party to or on behalf of the Indemnified Party, the Indemnified Party shall remit to the Indemnifying Party an amount equal to the amount of the net insurance proceeds actually received by the Indemnified Party on account of such Loss which duplicate, in whole or in part, the payment made by the Indemnifying Party to or on behalf of the Indemnified Party.

(d) In connection with any actual or threatened Third Party Claims by, or actual or threatened litigation or other disputes with, Third Parties relating to Assumed Liabilities or Excluded Liabilities, any such claims, litigation and disputes being referred to as “claims” for purposes of this Section 9.3(d), the Indemnified Party shall cooperate in the defense by the Indemnifying Party of such claim (and the Indemnified Party and the Indemnifying Party agree with respect to all such claims that a common interest privilege agreement exists between them), including, (i) permitting the Indemnifying Party to discuss the claim with such officers, employees, consultants and representatives of the Indemnified Party as the Indemnifying Party reasonably requests, (ii) permitting the Indemnifying Party to have reasonable access to the properties, books, records, papers, documents, plans, drawings, electronic mail, databases and computers of the Indemnified Party at reasonable hours to review information and documentation relative to the claim, (iii) providing to the Indemnifying Party copies of documents and samples of the Product as the Indemnifying Party reasonably requests in connection with defending such claim, (iv) permitting the Indemnifying Party to conduct privileged interviews and witness preparation of officers, employees and representatives of the Indemnified Party as the Indemnifying Party reasonably requests, (v) preserving all properties, books, records, papers, documents, plans, drawings, electronic mail and databases included in the Purchased Assets relating to matters relating to Excluded Liabilities (in the case of the Purchaser) and Assumed Liabilities (in the case of Seller) in accordance with such Party’s corporate documents retention policies, or longer to the extent reasonably requested by the other Party in connection with any actual or threatened action that would reasonably be expected to result in a claim for indemnification hereunder, (vi) promptly collecting documents and extracting information from documents for the Indemnifying Party’s review and use, as the Indemnifying Party reasonably requests, or allowing the Indemnifying Party’s representatives to do the same, (vii) notifying the Indemnifying Party promptly of receipt by the Indemnified Party of any subpoena or other Third Party request for documents or interviews and testimony, (viii) providing to the Indemnifying Party copies of any documents produced by the Indemnified Party in response to or compliance with any subpoena or other Third Party request for documents, and (ix) permitting the Indemnifying Party to conduct such other reasonable investigations and studies, and take such other actions, as are reasonably necessary in connection with the Indemnifying Party’s defense or investigation of such claim. In connection with any claims, except to the extent inconsistent with the Indemnified Party’s obligations under Applicable Law and except to the extent that to do so would subject the Indemnified Party or its employees, agents or representatives to criminal or civil sanctions, (1) unless ordered by a court to do otherwise, the Indemnified Party shall not produce documents to a Third Party until the Indemnifying Party has been provided a reasonable opportunity to review, copy and assert privileges covering such documents, (2) the transfer to the Indemnified Party of documents covered by the Indemnifying Party’s attorney/client or work.
Section 9.4 Certain Procedures. The Indemnified Party shall give the Indemnifying Party prompt written notice (an “Indemnification Claim Notice”) (but in no event more than thirty (30) days after discovery) of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under Section 9.1(a) or Section 9.1(b); provided, however, that failure to give such notice shall not relieve the Indemnifying Party of its obligations hereunder except to the extent it shall have been materially prejudiced by such failure. Each Indemnification Claim Notice must contain a reasonable description of the claim and the nature and amount of such Losses (to the extent the nature and amount of such Losses are known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party (but in no event more than thirty (30) days after discovery) copies of all papers and official documents received in respect of any Losses. All indemnification claims in respect of a Party, its Affiliates or their respective directors, stockholders, members, officers, managers, employees and agents shall be made solely by such Party to this Agreement.

Section 9.5 Guaranty. Parent hereby agrees to be responsible for, and guarantee to Seller, the full performance by Purchaser, a wholly-owned subsidiary of Parent, and Opco, an indirect, wholly-owned subsidiary of Purchaser, and agrees to cause Purchaser and Opco to perform, all of their respective obligations and liabilities under or in connection with this Agreement, the Ancillary Agreements and the transactions contemplated hereby and thereby. The liability of Parent under this Section 9.5 shall be irrevocable, absolute and independent.

Section 9.6 Remedies Exclusive. Following the Closing, with the exception of remedies based on fraud, the remedies set forth in this Article IX shall constitute the sole and exclusive remedy for money damages and shall be in lieu of any other remedies for money damages that may be available to the Indemnified Parties under any other agreement or pursuant to any statutory or common law with respect to any Losses of any kind or nature incurred directly or indirectly resulting from or arising out of any of this Agreement, the Purchased Assets, the Assumed Liabilities or the Excluded Liabilities (it being understood that nothing in this Section 9.6 or elsewhere in this Agreement shall affect the Parties’ rights to specific performance or other similar non-monetary equitable remedies with respect to the covenants referred to in this Agreement to be performed after the Closing). The Parties each hereby waive any provision of any Applicable Law to the extent that it would limit or restrict the agreement contained in this Section 9.6.
ARTICLE X
MISCELLANEOUS PROVISIONS

Section 10.1 Confidentiality.

(a) Reference is made to that certain letter agreement dated July 28, 2011, by and between Seller and Parent (the “Confidentiality Agreement”). As used in this Section 10.1, the term “Evaluation Material” shall have the meaning assigned to such term in the Confidentiality Agreement. Upon the Closing, the Confidentiality Agreement shall expire and be of no further force and effect with respect to all Evaluation Material relating to the Product Business, the Purchased Assets or the Assumed Liabilities, but all such Evaluation Materials shall thereafter be governed by the provisions of Section 10.1(b), provided, however, such expiration of the Confidentiality Agreement shall in no way prejudice or adversely affect Seller’s ability to seek damages, or any other remedy available to Seller, with respect to a violation by Purchaser, Parent or Opco (or their respective Affiliates or representatives) of the Confidentiality Agreement prior to or after the Closing. Upon and after the Closing, the Confidentiality Agreement shall remain in full force and effect pursuant to its terms with respect to all other Evaluation Material that does not relate to the Product Business, the Purchased Assets or the Assumed Liabilities.

(b) From and after the Closing, all confidential information and all Evaluation Material relating to the Product Business, the Purchased Assets and the Assumed Liabilities shall constitute the “Purchaser Confidential Information” and shall be used by Seller solely as required to perform its obligations, exercise or enforce its rights under this Agreement (or any Ancillary Agreement), or comply with Applicable Law, and for no other purpose. Seller shall not disclose, or permit the disclosure of, any of the Purchaser Confidential Information to any Person except those Persons to whom such disclosure is necessary to permit Seller to perform its obligations, exercise or enforce its rights under this Agreement (or any Ancillary Agreement), or comply with Applicable Law. Seller shall treat, and will cause its Affiliates and the directors, officers, employees, agents, representatives and advisors of Seller or any of their Affiliates to treat, the Purchaser Confidential Information as confidential, using the same degree of care as Seller normally employs to safeguard its own confidential information from unauthorized use or disclosure, but in no event less than a reasonable degree of care.

(c) All confidential information obtained by Purchaser, Parent or Opco (or their respective Affiliates or representatives) other than the Purchaser Confidential Information (the “Seller Confidential Information”) shall be used by Purchaser, Parent and Opco solely as required to perform their respective obligations, exercise or enforce its rights under this Agreement (or any Ancillary Agreement), or comply with Applicable Law, and for no other purpose. Purchaser, Parent and Opco shall not disclose, or permit the disclosure of, any of Seller Confidential Information to any person except those persons to whom such disclosure is necessary to permit Purchaser, Parent and Opco to perform their respective obligations, exercise or enforce their respective rights under this Agreement (or any Ancillary Agreement), or comply with Applicable Law. Purchaser, Parent and Opco shall each treat, and will cause their respective Affiliates and the directors, officers, employees, agents, representatives and advisors of Purchaser, Parent and Opco or any of their Affiliates to treat, Seller Confidential Information as confidential, using the same degree of care as Purchaser,
Parent and Opco normally employs to safeguard its own confidential information from unauthorized use or disclosure, but in no event less than a reasonable degree of care.

(d) In the event any Party is requested pursuant to, or required by, Applicable Law to disclose any of any other Party’s Confidential Information (i.e., Seller Confidential Information or Purchaser Confidential Information, as applicable), it will notify the other Party in a timely manner so that such Party may seek a protective order or other appropriate remedy or, in such Party’s sole discretion, waive compliance with the confidentiality provisions of this Agreement. Each Party will co-operate in all reasonable respects, in connection with any reasonable actions to be taken for the foregoing purpose. In any event, the Party requested or required to disclose such Confidential Information may furnish it as requested or required pursuant to Applicable Law (subject to any such protective order or other appropriate remedy) without liability hereunder, provided that such Party furnishes only that portion of the Confidential Information which such Party is advised by a reasoned opinion of its counsel is legally required, and such Party exercises reasonable efforts to obtain reliable assurances that confidential treatment will be accorded such Confidential Information.

(e) Nothing in this Section 10.1 shall be construed as preventing or in any way inhibiting any Party from complying with Applicable Law governing activities and obligations undertaken pursuant to this Agreement, in any manner which it reasonably deems appropriate, including, for example, by disclosing to Governmental Authorities confidential or other information of the other Party.

Section 10.2 Notices. All notices, requests and other communications required or permitted under, or otherwise made in connection with, this Agreement, shall be in writing and shall be deemed to have been duly given (a) when delivered in person, (b) upon confirmation of receipt when transmitted by facsimile transmission, or (c) on the next Business Day if transmitted by national overnight courier (with confirmation of delivery), in each case, addressed as follows:

if to Seller, to:

InterMune, Inc.
3280 Bayshore Boulevard
Brisbane, CA 94005
Attention: General Counsel
Facsimile No.: (415) 466-2300

with a copy to (which shall not constitute notice):

Latham & Watkins LLP
140 Scott Drive
Menlo Park, CA 94025
Attention: Mark V. Roeder, Esq.
Facsimile No.: (650) 463-2600

if to Purchaser or Parent to:

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Vidara Therapeutics International Limited
Attention: Dr. Virinder Nohria
c/o Fairisle Management Limited
The Penthouse, Washington Mall I
20 Church Street
Hamilton HM 11
Bermuda
Facsimile No.: (441) 295-4614

if to Opco to:
Vidara Therapeutics Research Limited
Adelaide Chambers
Peter Street
Dublin 8
Ireland
Attention: David Kelly
Facsimile No.: 353-1-449-3251

with a copy to (which shall not constitute notice):
Burke, Warren, MacKay & Serritella, P.C.
330 North Wabash Avenue, Suite 2200
Chicago, IL 60611
Attention: Christopher R. Manning
Facsimile No.: (312) 840-7900

or to such other address or facsimile number as such Party may hereafter specify for the purpose by notice to the other parties hereto in accordance with the terms of this Section 10.2.

Section 10.3 Bulk Transfers. Purchaser waives compliance with the provisions of all Applicable Laws relating to bulk transfers in connection with the transfer of the Purchased Assets.

Section 10.4 Remedies Cumulative; Specific Performance. The rights and remedies of the Parties shall be cumulative (and not alternative). The Parties agree that irreparable damage would occur if any provision of this Agreement were not performed in accordance with the terms hereof and that the Parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement or to enforce specifically the performance of the terms and provisions of this Agreement in addition to any other remedy to which they are entitled at law or in equity, in each case without the requirement of posting any bond or other type of security.

Section 10.5 Further Assurances; Further Cooperation. Subject to the terms and conditions hereof, each of the Parties agrees to use commercially reasonable efforts to execute and deliver, or cause to be executed and delivered, all documents and to take, or cause to be taken, all actions that may be reasonably necessary or appropriate, in the reasonable opinion of counsel for each Party, to effectuate the provisions of this Agreement, provided that all such actions are in accordance with Applicable Law. From time to time, whether at or after the
Closing, (i) Seller shall execute and deliver such further documents or instruments of conveyance, transfer and assignment and take all such other action, at Purchaser’s sole expense, as Purchaser may reasonably require to more effectively convey, transfer and assign to Purchaser any and all ownership, right, title and interest in and to the Purchased Assets, including, without limitation, executing documents or instruments necessary to permit Purchaser to record the transfer, conveyance and/or assignment of any and all Product Intellectual Property with any Governmental Authority and (ii) Purchaser, Parent and Opco will execute and deliver such further instruments and take all such other action, at Seller’s sole expense, as Seller may reasonably require to more effectively assume the Assumed Liabilities. Upon reasonable request and during normal business hours, Purchaser, Parent, Opco and Seller shall cooperate with each other, and shall cause their respective representatives and Affiliates to cooperate with each other, after the Closing to ensure the orderly transition of the Purchased Assets and Assumed Liabilities to Purchaser and to minimize any disruption to the businesses of Seller, Purchaser, Parent and Opco that might result from the transactions contemplated hereby.

Section 10.6 Amendments and Waivers.

(a) Any provision of this Agreement may be amended or waived but only if, such amendment or waiver is in writing and is signed, in the case of an amendment, by each Party to this Agreement or, in the case of a waiver, by the Party against whom the waiver is to be effective. No waiver by any Party hereto of any term or condition of this Agreement in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement or any future occasions.

(b) No failure or delay by any Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right or power or privilege. The rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by Applicable Law.

Section 10.7 Expenses. Except as otherwise provided herein, all costs and expenses incurred in connection with this Agreement, including all third-party legal, accounting, financial advisory, consulting or other fees and expenses incurred in connection with the transactions contemplated hereby, shall be paid by the Party incurring such cost or expense.

Section 10.8 Binding Effect; Benefit; Assignment.

(a) The provisions of this Agreement shall be binding upon and shall inure to the benefit of the Parties and their respective successors and assigns. Except as provided under this Agreement, no provision of this Agreement is intended to confer any rights, benefits, remedies, obligations or liabilities hereunder upon any Person other than the Parties and their respective successors and assigns.

(b) Neither this Agreement nor any right, interest or obligation hereunder may be assigned by any Party hereto (other than to an Affiliate of the Party) without the prior written consent of the other Party hereto (which consent shall not be unreasonably withheld) and any attempt to do so will be void; provided, however, that after the Closing, such prior written
consent will not be required with respect to any assignment by any Party (a) to an Affiliate of such Party so long as such Party remains bound by the terms hereof, or (b) in connection with a reorganization, merger, statutory share exchange, consolidation or similar change of control transaction involving the Seller or sale or transfer of all or substantially all of the assets of Seller, or, in the case of Purchaser, a sale or transfer, regardless of form, involving all or substantially all of the assets associated with the Product Business. Except with respect to Section 8.14(a) of this Agreement which shall not apply to non-affiliated successors or assigns of Seller, and except with respect to Section 8.14(b) of this Agreement which shall not apply to non-affiliated successors or assigns of Purchaser, Parent and Opco, this Agreement is binding upon, inures to the benefit of and is enforceable by the Parties hereto and their respective successors and permitted assigns. For the avoidance of doubt, all obligations pursuant to Section 8.14(a) shall automatically and immediately terminate and cease to be enforceable against any non-affiliated successor or assign of Seller and all obligations pursuant to Section 8.14(b) shall automatically and immediately terminate and cease to be enforceable against any non-affiliated successor of Parent, Purchaser or Opco. Any attempt to assign this Agreement in violation of this Section 10.8(b) shall be void. Subject to this Section 10.8(b), any permitted assignee shall assume all obligations of its assignor under this Agreement pursuant to a written instrument reasonably acceptable to the other Parties. In addition, nothing in this Agreement shall preclude Purchaser from providing its lenders with a security interest in its rights under this Agreement in accordance with the terms of their security and collateral agreements in connection with any credit facility provided by such lenders to Purchaser or preclude such lenders from foreclosing upon such security interest in accordance with the terms of such security and collateral agreements (including, without limitation, by means of the sale of the assets or stock of Purchaser to a Third Party including Purchaser’s rights and responsibilities under this Agreement), and any such action by such lenders shall not be deemed to be a change of control for purposes of this Agreement.

(c) Nothing in this Agreement, express or implied, is intended to or shall confer upon any Person other than the Parties and their respective successors and permitted assigns any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

Section 10.9 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts of laws that would require the application of the laws of any other jurisdiction.

Section 10.10 Jurisdiction. The Parties hereto agree that any Proceeding seeking to enforce any provision of, or based on any matter arising out of or in connection with, this Agreement or the transactions contemplated hereby shall be brought in any federal court located in the State of Delaware or any Delaware state court, and each of the Parties hereby irrevocably consents to the jurisdiction of such courts (and of the appropriate appellate courts therefrom) in any such Proceeding and irrevocably waives, to the fullest extent permitted by law, any objection that it may now or hereafter have to the laying of the venue of any such Proceeding in any such court or that any such Proceeding brought in any such court has been brought in an inconvenient forum. Process in any such Proceeding may be served on any Party anywhere in the world, whether within or without the jurisdiction of any such court. Without limiting the foregoing, each Party agrees that service of process on such party as provided in Section 10.2 shall be deemed effective service of process on such Party.
Section 10.11 Waiver of Jury Trial. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

Section 10.12 Arbitration.

(a) With respect to any dispute, controversy or claim arising from or related to this Agreement or the breach thereof that is not an Excluded Claim ("Dispute"), such Dispute shall first be referred to an executive officer from each Party for attempted resolution by good faith negotiations. Any such Dispute shall be submitted to such senior executives no later than thirty (30) days following such request by any Party. Such executives shall attempt in good faith to resolve any such Dispute within thirty (30) days after the submission of the Dispute. In the event the executives are unable to resolve the Dispute, the Parties shall otherwise negotiate in good faith and use reasonable efforts to settle. If the Parties do not fully settle, and a Party wishes to pursue the matter, each such Dispute shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes of the American Arbitration Association ("AAA"), and judgment on the arbitration award may be entered in any court having jurisdiction thereof.

(b) The arbitration shall be conducted by a panel of three (3) persons experienced in the pharmaceutical business: within thirty (30) days after initiation of arbitration, each of Purchaser and Seller shall select one person to act as arbitrator and the two selected arbitrators shall select a third arbitrator within thirty (30) days of their appointment. If the arbitrators selected by Purchaser and Seller are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the AAA. The place of arbitration shall be San Francisco, California, and all proceedings and communications shall be in English.

(c) Any Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Any Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party’s compensatory damages. Each Party shall bear its own costs and expenses and attorneys’ fees and an equal share of the arbitrators’ fees and any administrative fees of arbitration.

(d) Except to the extent necessary to confirm an award or as may be required by law, no Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of each Party. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable Delaware statute of limitations.

(e) For clarity, this Section 10.12 shall not apply to any Excluded Claim with the result that Excluded Claims shall not be subject to resolution by arbitration in the absence of a separate agreement between the Parties to do so.
Section 10.13 Counterparts; Effectiveness. This Agreement may be signed in any number of counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. This Agreement shall become effective when each Party shall have received a counterpart hereof signed by the other Party. Until and unless each Party has received a counterpart hereof signed by the other Party hereto, this Agreement shall have no effect, and no Party shall have any right or obligation hereunder (whether by virtue of any other oral or written agreement or other communication). The exchange of a fully executed Agreement or any Ancillary Agreement (in counterparts or otherwise) by electronic transmission in .PDF format or by facsimile shall be sufficient to bind the Parties to the terms and conditions hereof and thereof.

Section 10.14 Entire Agreement. This Agreement, the Ancillary Agreements, the Confidentiality Agreement and each of the documents, instruments and agreements delivered in connection with the transactions contemplated by this Agreement, including each of the Exhibits, the Schedules, and the Seller Disclosure Schedule, constitute the entire agreement between the Parties with respect to the subject matter of this Agreement and supersede all prior agreements and understandings, both oral and written, between the Parties with respect to the subject matter of this Agreement.

Section 10.15 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction or other Governmental Authority to be invalid, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions of this Agreement shall remain in full force and effect and shall in no way be affected, impaired or invalidated so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any Party. Upon such a determination, the Parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible in an acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the fullest extent possible.

Section 10.16 Time is of the Essence. Time is of the essence with respect to the performance of this Agreement.

(Signatures Pages Follow)

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Agreement Date.

<table>
<thead>
<tr>
<th>Company</th>
<th>By:</th>
<th>Name:</th>
<th>Title:</th>
</tr>
</thead>
<tbody>
<tr>
<td>VIDARA THERAPEUTICS INTERNATIONAL LIMITED</td>
<td>/s/ Virinder Nohria</td>
<td>Virinder Nohria</td>
<td>President</td>
</tr>
<tr>
<td>VIDARA THERAPEUTICS HOLDINGS LLC</td>
<td>/s/ Bala Venkataraman</td>
<td>Bala Venkataraman</td>
<td>Chairman and Treasurer</td>
</tr>
<tr>
<td>VIDARA THERAPEUTICS RESEARCH LIMITED</td>
<td>/s/ David G. Kelly</td>
<td>David G. Kelly</td>
<td>Director &amp; Chief Financial Officer</td>
</tr>
<tr>
<td>INTERMUNE, INC.</td>
<td>/s/ John C. Hodgman</td>
<td>John C. Hodgman</td>
<td>Chief Financial Officer and Senior Vice President, Finance</td>
</tr>
</tbody>
</table>

*Signature Page to Asset Purchase Agreement*
AMENDMENT TO ASSET PURCHASE AGREEMENT

This AMENDMENT TO ASSET PURCHASE AGREEMENT (the “Amendment”), dated as of June 18, 2012, is made and entered into by and among Vidara Therapeutics International Limited, an Irish company (“Purchaser”), Vidara Therapeutics Holdings LLC, a Delaware limited liability company (“Parent”), Vidara Therapeutics Research Limited, an Irish company (“Opco”) and InterMune, Inc., a Delaware corporation (“Seller”). Capitalized terms used herein and not otherwise defined herein shall have the meaning given such terms in the Agreement (as defined below).

RECITALS

WHEREAS, Purchaser, Parent, Opco and Seller entered into that certain Asset Purchase Agreement dated as of May 17, 2012 (the “Agreement”);

WHEREAS, due to a scrivener’s error, the attachment to Section 3.13(c) of the Seller Disclosure Schedule erroneously set forth the number of “Vials Sold Canada” and “Vials Sold US”;

WHEREAS, due to a scrivener’s error, Schedule 1.1(d) to the Agreement and Section 3.7 of the Seller Disclosure Schedule included an agreement which is not an Assumed Contract; and

WHEREAS, Purchaser, Parent, Opco and Seller desire to amend the Agreement as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the promises, representations, warranties, covenants and agreements contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound hereby, agree as follows:

Section 1.1 Amendments.

(a) The attachment to Section 3.13(c) of the Seller Disclosure Schedule is hereby amended and restated in its entirety as set forth in Exhibit A hereto.

(b) The following agreement is hereby deleted in its entirety from Schedule 1.1(d) to the Agreement and Section 3.7 of the Seller Disclosure Schedule: Second Amended and Restated Materials Transfer Agreement between National Jewish Health and InterMune, Inc. dated November 22, 2010.

Section 1.2 Miscellaneous Provisions.

(a) Article X of the Agreement shall apply hereto mutatis mutandis.

(Signature Pages Follow)
IN WITNESS WHEREOF, the Parties have caused the Amendment to be executed as of the first date written above.

VIDARA TERAPEUTICS INTERNATIONAL LIMITED

By: /s/ Bala Venkataraman
Name: Bala Venkataraman
Title: Director

VIDARA TERAPEUTICS HOLDINGS LLC

By: /s/ Virinder Nohria
Name: Virinder Nohria
Title: President

VIDARA TERAPEUTICS RESEARCH LIMITED

By: /s/ David G. Kelly
Name: David G. Kelly
Title: Director and Chief Financial Officer

Signature Page to Amendment to Asset Purchase Agreement
INTERMUNE, INC.

By: /s/ John C. Hodgman
Name: John C. Hodgman
Title: Chief Financial Officer and Senior Vice President, Finance

Signature Page to Amendment to Asset Purchase Agreement
CONSOLIDATED SUPPLY AGREEMENT

THIS CONSOLIDATED SUPPLY AGREEMENT (this “AGREEMENT”), is made effective as of the 31 day of July 2013 (the “EFFECTIVE DATE”) by and between Vidara Therapeutics Research, Ltd. (“VIDARA”), an Irish corporation, having an address at Adelaide Chambers, Peter Street, Dublin 8, Ireland and Boehringer Ingelheim RCV GmbH & Co KG (“BI RCV”), an Austrian limited liability partnership, having its registered office at Dr. Boehringer-Gasse 5 – 11, A-1121 Vienna, Republic of Austria (and successor-in-interest of Boehringer Ingelheim Austria GmbH). VIDARA and BI RCV may be referred to herein each individually as a “Party” and jointly as the “Parties.”

WHEREAS, VIDARA is the exclusive licensee of and the holder of an exclusive sublicense under a license from GENENTECH (as defined herein) to manufacture, use and sell recombinant human gamma-interferon (“INTERFERON GAMMA 1b”, as further described herein) products in the USA and certain other territories, which INTERFERON GAMMA 1b is approved by the FDA for the indications Chronic Granulomatous Disease and severe, malignant Osteopetrosis, and is sold in the USA under the trade-mark ACTIMMUNE® (the “GENENTECH PRODUCT”, as further described herein); and

WHEREAS, Boehringer Ingelheim International GmbH (BID, an affiliate of BI RCV and BI Pharma KG (as defined hereinafter), holds an exclusive license from GENENTECH to manufacture, use and sell INTERFERON GAMMA 1b in certain other territories, and is the registration-holder for an INTERFERON GAMMA 1b product in certain countries for the indication Chronic Granulomatous Disease and is sold in Europe under the trade-mark IMUKIN® (the “BI PRODUCT”, as further described herein); and

WHEREAS, BI RCV and its affiliate BI Pharma KG (as defined hereinafter) own facilities specialised for cGMP manufacture of biopharmaceuticals and manufactures and supplies the BI PRODUCT to BII to meet BII’s needs with respect thereto; and

WHEREAS, InterMune, Inc. (“InterMune”) and BI RCV had entered into that certain Supply Agreement dated June 29, 2007 (“RESTATED SUPPLY AGREEMENT”) pursuant to that certain Termination Agreement dated the 6th of June 2007 (“TERMINATION AGREEMENT”) whereby InterMune and BI RCV had agreed, among other things, to terminate that certain Data Transfer, Clinical Trial and Market Supply Agreement dated the 27th of January 2000, as amended (the “ORIGINAL SUPPLY AGREEMENT”) and enter into such Restated Supply Agreement to replace the ORIGINAL SUPPLY AGREEMENT; and

WHEREAS, InterMune and BI RCV entered into the Amended and Restated Supply Agreement (“AMENDED AND RESTATED SUPPLY AGREEMENT”) effective as of May 15,
WHEREAS, the Parties wish to enter into this CONSOLIDATED SUPPLY AGREEMENT ("AGREEMENT") to replace the AMENDED AND
RESTATED SUPPLY AGREEMENT to amend and consolidate the AMENDED AND RESTATED SUPPLY AGREEMENT which will set forth the terms and
conditions pursuant to which BI RCV will continue on a going forward basis to manufacture and supply to VIDARA and VIDARA will purchase from BI
RCV finished INTERFERON GAMMA 1b product to meet VIDARA’s needs with respect thereto.

NOW, THEREFORE, in consideration of the foregoing recitals which are hereby incorporated by reference herein and for other good and valuable
consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

1. DEFINITIONS

The following capitalized definitions will apply throughout this Agreement:

1.1 AFFILIATE means (i) any corporation or business entity fifty percent (50 %) or more of the voting stock of which is and continues to be owned directly
or indirectly by any party hereto; (ii) any corporation or business entity which directly or indirectly owns fifty percent (50 %) or more of the voting stock of
any party hereto; or (iii) any corporation or business entity under the direct or indirect control of such corporation or business entity as described in (i) or (ii).

1.2 AMENDED AND RESTATED SUPPLY AGREEMENT has the meaning ascribed to it in the recitals of this AGREEMENT.

1.3 APPROVAL means a regulatory approval required from a HEALTH AUTHORITY in order to manufacture BBS or PRODUCT for use in clinical trials or
market supply as applicable, in the applicable jurisdiction.

1.4 BI RCV'S IMPROVEMENTS shall mean all INFORMATION comprising any inventions, modifications and/or improvements to the VIDARA
TECHNOLOGY or to the GENENTECH TECHNOLOGY, that BI RCV or BI Pharma KG conceive of or reduce to practice pursuant to the ORIGINAL SUPPLY
AGREEMENT, RESTATED SUPPLY AGREEMENT and/or this AGREEMENT, either individually or in conjunction with one or more third parties or BI
Affiliates, including all patent and patent applications covering any of the foregoing.

1.5 BI RCV'S TECHNOLOGY means all INFORMATION in the field of manufacturing and testing of biopharmaceuticals, including without limitation the
MANUFACTURING PROCESS but only to the extent that it relates solely to BI PRODUCT, and including all patents and patent applications covering any
of the foregoing, that are owned or CONTROLLED by BI RCV or BI Pharma KG during the term of the ORIGINAL SUPPLY AGREEMENT, the
RESTATED SUPPLY AGREEMENT and/or this AGREEMENT and that are related to or
useful in BI RCV’s carrying out its obligations under this AGREEMENT, but specifically excluding VIDARA’S TECHNOLOGY and BI RCV’S IMPROVEMENTS.

1.6 BII means Boehringer Ingelheim International GmbH, an AFFILIATE of BI RCV and BI Pharma KG.

1.7 BI PHARMA KG means BI RCV’s AFFILIATE BI Pharma KG, FRG-88397 Biberach an der Riss, Birkendorfer Straße 65, Germany, owning an FDA inspected and cGMP-certified facility.

1.8 BI PRODUCT means the liquid formulation of INTERFERON GAMMA 1b approved in various countries for which BII has acquired rights from GENENTECH for the treatment of Chronic Granulomatous Disease, and manufactured by BI RCV and BI Pharma KG for sale in Europe under the trademark IMUKIN®.

1.9 BLA means a Biologics License Application, as defined by the regulations promulgated under the FD&C ACT, and any equivalent application with respective HEALTH AUTHORITIES.

1.10 BULK BIOLOGICAL SUBSTANCE (BBS) means a bulk form of the PRODUCT. This bulk form is *** .

1.11 BULK SPECIFICATIONS mean the specifications for BBS listed in Exhibit 1.

1.12 cGMP means the current Good Manufacturing Practices of all applicable HEALTH AUTHORITIES, including without limitation the FDA, and including without limitation all applicable rules, regulations, guides and guidance, such as 21 C.F.R. parts 210 and 211 and parts 600 and 610.

1.13 CMC means the Chemistry, Manufacturing, and Controls content of a submission to a HEALTH AUTHORITY.

1.14 COA means a Certificate of Analysis, a document listing testing parameters, specifications and test results (in a format and detail as listed in Exhibit 2).

1.15 COC means a Certificate of Compliance confirming compliance with cGMP regulations and signed by BI RCV’s authorised Qualified Person, the Head of Production and the Head of Quality Assurance (in a format and such detail as listed in Exhibit 3).

1.16 COMPONENTS means, collectively, all raw materials, consumables, resins, equipment dedicated to the PRODUCT, and materials required to process and package for shipment the PRODUCT in accordance with the SPECIFICATIONS.

1.17 CONFIDENTIAL INFORMATION means any proprietary INFORMATION (a) disclosed by one Party to the other from and after the effective date of the ORIGINAL SUPPLY AGREEMENT, or (b) developed by either Party pursuant to this AGREEMENT, except for INFORMATION which (i) is already in the public domain at the time of its disclosure to the receiving Party; (ii) becomes part of the public domain through no wrongful action or omission

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
of the receiving Party after disclosure to the receiving Party; (iii) is already known to the receiving Party at the time of disclosure as evidenced by the receiving Party’s written records; or (iv) is independently developed by the receiving Party without the use or application of the disclosing Party’s proprietary information.

1.18 CONTROLLED means, with respect to any material, INFORMATION or intellectual property right, possession of the ability by a Party to grant access, a license, or a sublicense to such material, INFORMATION or intellectual property right as provided for herein without violating an agreement with a Third Party as of the time such Party would be first required hereunder to grant the other Party such access, license or sublicense.

1.19 EURO means a euro, which is the European unit of currency.

1.20 FDA means the United States Food and Drug Administration and any successor agency thereto.

1.21 FD&C ACT means the United States Food, Drug & Cosmetic Act as amended from time to time and any supplements thereunder, and any equivalent regulation of any HEALTH AUTHORITIES.

1.22 FINAL RELEASE means the release of PRODUCT by VIDARA or its licensees for clinical trial use or market supply, as applicable.

1.23 GENENTECH means Genetech, Inc. with its principal place of business at 1 DNA Way, South San Francisco, CA, 94080-4990.

1.24 GENENTECH PRODUCT means the formulation of INTERFERON GAMMA 1b which was manufactured in the US by GENENTECH for sale under the trademark ACTIMMUNE and approved by the FDA for the treatment of Chronic Granulomatous Disease and Osteopetrosis.

1.25 GENENTECH TECHNOLOGY means all INFORMATION relating to the manufacture, use or sale of INTERFERON GAMMA 1b that is licensed to either Party pursuant to an agreement with GENENTECH, including without limitation the MANUFACTURING PROCESS, and all patents and patent applications covering such INFORMATION.

1.26 HEALTH AUTHORITIES mean all regulatory authorities having jurisdiction over the manufacture, use and/or sale of the PRODUCT in the TERRITORY, including but not limited to the FDA.

1.27 INFORMATION means (a) techniques, data, inventions, practices, methods, knowledge, know-how, skill, experience, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, regulatory submissions, correspondence and communications, marketing, pricing, distribution, cost, sales, manufacturing, patent and legal data or descriptions, compositions of matter, assays and biological materials, and (b) all intellectual property rights in and to any of the foregoing.
1.28 INTERFERON-GAMMA 1b means the recombinant human Interferon-Gamma 1b derived from *** that is the active ingredient in ACTIMMUNE®. The relevant amino acid sequence is set forth in Exhibit 4.

1.29 VIDARA’S TECHNOLOGY means all INFORMATION that was or is CONTROLLED either by InterMune or VIDARA during the term of the ORIGINAL SUPPLY AGREEMENT, the RESTATED SUPPLY AGREEMENT, the AMENDED AND RESTATED SUPPLY AGREEMENT and/or the term of this AGREEMENT that is related to or useful in BI RCV’s manufacture of PRODUCT hereunder and that was acquired by VIDARA from InterMune or thereafter developed by VIDARA, and all patents and patent applications covering any of the foregoing; provided that “VIDARA’S TECHNOLOGY” shall not include any INFORMATION (i) owned or CONTROLLED by BI RCV prior to the effective date of the ORIGINAL SUPPLY AGREEMENT, (ii) conceived of, or reduced to practice or acquired by BI RCV outside the ORIGINAL SUPPLY AGREEMENT, or the RESTATED SUPPLY AGREEMENT, or the AMENDED AND RESTATED SUPPLY AGREEMENT during their respective terms or outside this AGREEMENT during the term hereof, or (iii) the GENENTECH TECHNOLOGY.

1.30 RESERVED.

1.31 MANUFACTURER’S RELEASE means the release of the PRODUCT by BI RCV to VIDARA or its designee.

1.32 MANUFACTURING PROCESS means the process for fermentation, purification, filling, labeling and packaging of BBS and PRODUCT, as described in Exhibit 5.

1.33 MATERIAL SUPPLY BREACH means a failure of BI RCV: (a) to supply to VIDARA at *** of VIDARA’s binding forecasted requirements of PRODUCT (or actual orders, if less) that are due for delivery by the designated delivery date during the then-current calendar quarter; or (b) to repeatedly materially violate against cGMP.

1.34 ORIGINAL SUPPLY AGREEMENT has the meaning ascribed to it in the recitals of this AGREEMENT.

1.35 PRODUCT shall mean a finished product consisting of formulated INTERFERON GAMMA 1b filled into the designated containers for clinical supply and for market supply, as described in Exhibit 6, or shall mean a finished product of formulation buffer filled into the designated containers for clinical supply (placebo).

1.36 PROJECT MANAGER means the responsible person designated by each Party to be responsible for the communication of all information concerning this AGREEMENT. As of the Effective Date, the person designated as VIDARA’s PROJECT MANAGER and the person designated as BI RCV’s PROJECT MANAGER are listed in Exhibit 7. Either Party may change its own designated PROJECT MANAGER by providing written notice thereof to the other Party.

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
1.37 PRODUCT SPECIFICATIONS mean the specifications for the PRODUCT as set forth in Exhibit 8, or as otherwise agreed by the Parties in writing.

1.38 PROJECT TEAM means the team as listed in Exhibit 7 and described in Section 6.1.

1.39 QUALITY AGREEMENT means that Amended and Restated Quality Agreement dated May 15, 2012 between the Parties.

1.40 QUALITY ASSURANCE REQUIREMENTS mean those requirements set forth in the QUALITY AGREEMENT.

1.41 RESTATED SUPPLY AGREEMENT has the meaning ascribed to it in the recitals of this AGREEMENT.

1.42 STEERING COMMITTEE means the committee as listed in Exhibit 9 and described in Section 6.2.

1.43 TERMINATION AGREEMENT has the meaning ascribed to it in the recitals of this AGREEMENT.

1.44 TERRITORY means the US, Japan and all additional territories, including but not limited to Canada, as to which VIDARA has or may acquire the right to manufacture, use or sell INTERFERON GAMMA 1b products during the term of this AGREEMENT.

1.45 US means the United States of America.

2. GENERAL

2.1 VIDARA’s Tasks and Responsibilities

2.1.1 Support

VIDARA shall timely send all documentation, and otherwise timely provide all information and other assistance, reasonably requested by BI RCV for use under this AGREEMENT. VIDARA shall provide such reasonable technical support at its own expense, which support shall include access to VIDARA’s expert personnel upon reasonable notice and at such reasonable times as the Parties may agree.

2.1.2 Contact with Health Authorities

2.1.2.1 VIDARA, as the license holder for the GENENTECH PRODUCT in the US, shall have the overall responsibility regarding all contacts with the HEALTH AUTHORITIES and shall be solely responsible for filing all regulatory documents required by any HEALTH AUTHORITIES. BI RCV shall support VIDARA in all matters regarding the manufacturing and quality control of PRODUCT as reasonably requested by VIDARA, but VIDARA shall be the leading Party, responsible for co-ordination of all regulatory matters.
2.1.2.2 VIDARA will notify BI RCV in due time, but in no event later than five (5) business days in advance of any meeting with any HEALTH AUTHORITIES with regard to manufacture, supply and quality control of the PRODUCT manufactured by BI RCV or BI Pharma KG under this AGREEMENT. BI RCV shall have the right to participate in such meetings with such HEALTH AUTHORITIES during the portion of such meetings relating to BI RCV’s or BI Pharma KG’s manufacture, supply and quality control of the PRODUCT.

2.1.2.3 BI RCV will be responsible for drawing up the annual report required by the HEALTH AUTHORITIES reasonably in advance of the due date, and will be responsible of matters regarding the manufacture of PRODUCT. VIDARA shall submit such report to the HEALTH AUTHORITIES and shall provide BI RCV with a copy of the finally submitted report.

2.1.3 Shipment of Material by VIDARA

Any materials, e.g. samples, sent by VIDARA (or by a third party on behalf of VIDARA) to BI RCV shall be made by shipment from VIDARA’s facility (or the third party’s facility, as the case may be) to BI RCV’s facility in Vienna. Shipping costs including insurance will be borne by VIDARA, and risk of loss in transit shall lie with VIDARA.

2.2 BI RCV’s Tasks and Responsibilities

2.2.1 Regulatory Support

2.2.1.1 BI RCV agrees to co-operate with VIDARA in obtaining and maintaining all US governmental approvals and registrations relevant to the CMC section of the registration dossier (and their foreign equivalents) as requested by VIDARA.

2.2.1.2 The Parties shall consult with each other concerning the scope and content of all regulatory filings, and shall jointly define the requirements for the necessary PRODUCT registration with the FDA so that BI RCV shall be able to fulfill its obligations under this AGREEMENT with respect to the CMC portion of such PRODUCT registration. With respect to any part of the CMC portion which contains BI RCV and/or BI Pharma KG INFORMATION, BI RCV shall be provided an opportunity to review and comment on such parts prior to submission to a HEALTH AUTHORITY as set forth in the QUALITY AGREEMENT.

2.2.2 Format and Content of Documents. BI RCV’s Quality Management System demands a special format for certain documents (i.e. batch records, testing procedures, technical reports) which is binding. For those documents where a binding format is not obligatory the Parties shall agree in writing on a master format. With respect to the dates contained in these documents, and in particular in all reports and when dates occur in connection with signatures, the European writing style shall apply. The order shall be as follows: dd / mm / yy (day/month/year).

3. MANUFACTURE AND SUPPLY

3.1 General

3.1.1 BI RCV shall supply to VIDARA BBS or PRODUCT for the treatment or prevention of any human disease or condition, except for

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.

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cardiac or cardiovascular disease or condition. VIDARA shall purchase from BＩRCV, PRODUCT for the treatment of any human disease or condition, except for the treatment or prevention of any type of cardiac or cardiovascular condition. This provision does not in any way restrict BI RCV’s right to manufacture BI PRODUCT.

3.1.2 All BBS manufactured by BI RCV hereunder, and all PRODUCT manufactured and supplied to VIDARA by BI RCV hereunder, shall be manufactured and supplied in accordance with the BBS SPECIFICATIONS and PRODUCT SPECIFICATIONS, the cGMP requirements, the QUALITY ASSURANCE REQUIREMENTS as set forth in the QUALITY AGREEMENT and all applicable laws, regulations and ordinances of the jurisdiction in which such manufacture occurs.

3.1.3 BI RCV shall manufacture BBS according to the BULK SPECIFICATIONS. BI RCV shall manufacture PRODUCT according to PRODUCT SPECIFICATIONS for clinical supply and tier market supply. BBS for clinical and market supply shall be manufactured at BI RCV and transferred to BI Pharma KG for vialing, labeling (but only for market supply) and packaging. Manufacturing and filling of vials, labeling (but only for market supply) as well as the packaging and storing of PRODUCT shall be in accordance with the PRODUCT SPECIFICATIONS, the cGMP requirements, the QUALITY ASSURANCE REQUIREMENTS as set forth in the QUALITY AGREEMENT and all applicable laws, regulations and ordinances of the jurisdiction in which such manufacturing and/or filling occurs. Notwithstanding the fact that BI RCV takes BI Pharma KG as a toll manufacturer for filling, labeling (for market supply) and packaging of PRODUCT, BI RCV takes responsibility for the manufacture and supply of PRODUCT to VIDARA in accordance with the terms and conditions of this AGREEMENT.

3.2 Forecasts

3.2.1 Beginning with calendar quarter commencing on the 1st of July 2013, VIDARA shall provide a rolling forecast for the next twelve (12) quarters (36 months). Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
3.2.2 If VIDARA requires more PRODUCT than is set forth in the current firm forecast, BI RCV shall use commercially reasonable efforts in good faith to supply VIDARA with PRODUCT as requested; provided that for the amounts of PRODUCT in excess of such forecast which BI RCV is unable to supply, despite such commercially reasonable efforts, VIDARA may use a secondary source manufacturer in accordance with the procedures set forth in Section 3.7.

3.2.3 If VIDARA reduces the forecast *** , then VIDARA shall be obligated to pay for PRODUCT which was not ordered *** . Similarly, if VIDARA reduces the forecast *** , then VIDARA shall be obligated to pay for PRODUCT which was not ordered *** .

3.3 Purchase Orders

3.3.1 VIDARA shall be obligated to purchase amounts of PRODUCT in full lot size of *** under this Agreement consistent with the binding/nonbinding rolling forecast set forth in Section 3.2 above. At minimum, VIDARA shall order *** of PRODUCT per calendar year beginning in *** . When purchasing PRODUCT hereunder, VIDARA shall submit written purchase orders to BI RCV. To the extent that the terms of a purchase order or of BI RCV’s or BI Pharma KG’s “GENERAL CONDITIONS OF SALE” are inconsistent with the terms of this AGREEMENT, this AGREEMENT shall prevail.

3.3.2 BI RCV shall guarantee that at the date of FINAL RELEASE all PRODUCT supplied to VIDARA shall have a minimum residual shelf life of not less *** of PRODUCT shelf life, provided that VIDARA shall strictly fulfill its contractual timelines regarding FINAL RELEASE as set forth in Sections 3.5 and 5.3.

3.3.3 Subject to Section 3.4, BI RCV shall ship all PRODUCT as set forth in Section 3.5 by the date and in the quantities specified in the applicable purchase order. BI RCV shall be obligated to accept any purchase order within the range of permitted variation in the forecasted quantities as set forth in Section 3.2.1. and 3.2.2. Any other purchase order shall be binding on BI RCV only if it is accepted by BI RCV, which acceptance shall not be unreasonably withheld. If BI RCV does not accept such a purchase order, then VIDARA may use a secondary source manufacturer for such purchase order in accordance with the procedures set forth in Section 3.7.

3.3.4 VIDARA shall be obligated to buy and BI RCV shall be obligated to sell only the quantities of PRODUCT which are subject to a purchase order accepted by BI RCV; provided that BI RCV shall accept sufficient purchase orders from VIDARA annually to meet its

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obligations pursuant to Section 3.3.1 and in accordance with the rolling forecast model pursuant to Section 3.2.1. Any purchase order (or portion thereof) for which VIDARA has not received a written rejection from BI RCV within thirty (30) business days of BI RCV’s receipt of such purchase order shall be deemed accepted by BI RCV. With respect to PRODUCTS ordered by VIDARA for its clinical supply requirements, the number of vials supplied by BI RCV shall not exceed the number of vials ordered by VIDARA, provided, however, that if the number of vials BI RCV is able to supply falls below the number of vials ordered by VIDARA in such purchase order and such lesser number is within a reasonable range of the number ordered by VIDARA, BI RCV shall notify VIDARA in writing and inquire as to whether such lesser number of vials is acceptable and if not, whether BI RCV should produce an additional batch of BBS to produce enough vials to satisfy VIDARA’s purchase order. If VIDARA notifies BI RCV that such lesser number of vials is acceptable to VIDARA, then the applicable purchase order shall be deemed to be amended to provide for such lesser number of vials and BI RCV shall be deemed to have accepted such purchase order in accordance with Section 3.3. On the other hand, if VIDARA notifies BI RCV that BI RCV should manufacture an additional batch of BBS to produce the number of vials ordered by VIDARA in its purchase order submitted to BI RCV, then BI RCV shall be obligated to produce the additional batch of BBS, VIDARA shall be obligated to purchase any excess vials of PRODUCT produced by BI RCV from such additional batch of BBS and the purchase order submitted to BI RCV by VIDARA shall be deemed amended to account for any excess vials resulting from the additional batch of BBS and such purchase order shall be deemed accepted by BI RCV in accordance with Section 3.3.

3.4 Shipment of Product and Material by BI RCV

3.4.1 The PRODUCT and all material (e.g. samples) shall be shipped either BI Pharma KG, FRG 88397 Biberach an der Riss, Germany or BI RCV’s facility in Vienna, Austria, as the case may be, to VIDARA or as directed by VIDARA, in accordance with Incoterms 2010 as published by the International Chamber of Commerce and in accordance with the QUALITY AGREEMENT. VIDARA’s designated carrier shall be used to ship PRODUCT to the site designated by VIDARA. BI RCV shall use commercially reasonable efforts to notify VIDARA in writing upon loading of the PRODUCT onto such designated carrier. The Parties acknowledge and agree that the only deviation from the definition of the DRUG PRODUCT onto the carrier such that shall be responsible and bear the cost the VIDARA designated carrier. Risk of loss in transit shall lie with VIDARA.

3.4.2 BI RCV will provide or will have provided assistance to VIDARA regarding necessary procedures for exportation and/or importation of PRODUCT.

3.5 Testing and Rejection

3.5.1 Within business days of its receipt of PRODUCT at such destination as may be designated by VIDARA, VIDARA may perform such tests and samplings as are

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appropriate to determine whether such PRODUCT meets the applicable PRODUCT SPECIFICATIONS. If VIDARA refuses acceptance of PRODUCT, then VIDARA shall inform BI RCV in writing within *** further business days of any aspect in which such PRODUCT fails to conform to the PRODUCT SPECIFICATIONS. If BI RCV does not receive such a notice within *** business days of VIDARA’s receipt of such PRODUCT, then VIDARA shall be deemed to have accepted the PRODUCT; provided that VIDARA shall have the right to revoke its acceptance of such goods if it later discovers latent defects not reasonably discoverable at the time of receipt.

3.5.2 If BI RCV receives a notice from VIDARA pursuant to Section 3.5.1 that VIDARA does not accept any PRODUCT supplied hereunder, then BI RCV shall immediately start retesting the PRODUCT using the retained samples in order to evaluate process issues and other reasons for such non-compliance.

3.5.3 Regardless of whether BI RCV agrees with VIDARA’s rejection of such PRODUCT, if requested in writing by VIDARA, BI RCV shall use reasonable efforts to promptly replace such allegedly defective PRODUCT, the costs of which shall be borne as set forth in Section 3.5.4.

3.5.4 In the event that BI RCV’s re-testing does not verify VIDARA’s reasons for rejecting such PRODUCT and VIDARA is convinced by BI RCV and agrees with BI RCV that VIDARA’s reasons for rejecting such PRODUCT are unjustified, VIDARA shall pay BI RCV reasonable internal and external costs for conducting such re-testing; provided, however, that, if VIDARA is not convinced and does not agree that VIDARA’s reasons for rejecting such PRODUCT are unjustified, the Parties shall mutually agree on an independent laboratory that shall determine by applying validated product-specific analytical methods whether such PRODUCT meets the PRODUCT SPECIFICATIONS. The conclusions of this independent laboratory shall be binding upon both Parties. If such laboratory determines that such PRODUCT does meet the PRODUCT SPECIFICATIONS, then VIDARA shall bear the costs for such independent laboratory and for any replacement PRODUCT manufactured and supplied to VIDARA by BI RCV pursuant to Section 3.5.3. If such laboratory determines that such PRODUCT does not meet the PRODUCT SPECIFICATIONS, then BI RCV shall bear the costs for such independent laboratory and for any such replacement of PRODUCT.

3.5.5 Neither Party may destroy any PRODUCT alleged not to meet the PRODUCT SPECIFICATIONS until the independent laboratory determines whether such PRODUCT meets the applicable PRODUCT SPECIFICATIONS and provides written notification to the Parties with respect to such determination, unless BI RCV accepts VIDARA’s basis for such rejection. Thereafter, BI RCV shall have the obligation to destroy or have destroyed, at its cost, all such rejected PRODUCT. Upon BI RCV’s written request and at BI RCV’s cost, VIDARA shall either destroy or return to BI RCV any rejected PRODUCT. The Parties agree that in the event of destruction of PRODUCT, the method of such destruction shall be in compliance with all applicable laws, rules and regulations.

3.5.6 Claims on account of quantity, loss or damages to PRODUCT (other than claims that such PRODUCT does not meet the PRODUCT SPECIFICATIONS and latent defects not reasonably detectable upon inspection) will be dispatched by VIDARA in writing within ten (10) business days following receipt thereof. BI RCV shall use reasonable efforts to replace the

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quantity of goods which such claims apply, which replacement shall be at VIDARA’s expense unless such claims are due to the negligence of BI RCV.

3.6 Second Source Manufacturer

3.6.1 BI RCV acknowledges that it is critical that VIDARA be ensured continuity of supply of PRODUCT for use in clinical trials and market supply. BI RCV shall ensure continuity of supply of PRODUCT for use in clinical trials and market supply. Nevertheless, due to the potentially growing market demand of PRODUCT, BI RCV’s ability to manufacture and supply PRODUCT shall be carefully observed. Should at any time BI RCV have any indication that continuity of supply can not be ensured, BI RCV shall immediately inform VIDARA thereof in writing. In this event the matter would be immediately forwarded to the STEERING COMMITTEE to discuss second source manufacture of PRODUCT reasonably and in good faith.

3.6.2 In the event the STEERING COMMITTEE decides that it is appropriate for VIDARA to establish a second source manufacturer, VIDARA agrees to provide the first opportunity to qualify as a second source manufacturer for PRODUCT to a BI RCV AFFILIATE. If such an AFFILIATE is – as foreseeable – unable to supply VIDARA’s PRODUCT requirements then VIDARA shall be free to choose an alternate supplier. In this case BI RCV shall assist VIDARA in transferring the MANUFACTURING PROCESS to a third party supplier by providing reasonable technical assistance and documentation as necessary for a transfer to a party well skilled in the manufacture of such biotech products at VIDARA’s cost.

3.6.3 In addition, the parties, through the STEERING COMMITTEE shall work together in good faith to develop a risk mitigation plan to minimise any risk of interruption in the supply of PRODUCT for use in clinical trials and market supply, which plan may include, among other things, production of excess PRODUCT or materials relating thereto (e.g., BBS) that can be used as a buffer and/or the off-site storage of certain PRODUCT or materials relating thereto.

3.7 Material Supply Breach

3.7.1 In the event of a MATERIAL SUPPLY BREACH, VIDARA shall provide BI RCV written notification of such MATERIAL SUPPLY BREACH. Upon BI RCV’s receipt of such notice and failure to cure such MATERIAL SUPPLY BREACH within the timetable and activity plan agreed upon the Parties to cure such MATERIAL SUPPLY BREACH, VIDARA shall have the right to purchase from a second source manufacturer, to be agreed upon within the STEERING COMMITTEE in accordance with Section 3.6, such amounts of PRODUCT as necessary to offset BI RCV’s shortfall in fulfilling VIDARA’s purchase orders for such PRODUCT (or the anticipated shortfall, in the event of repeated (maximum two (2) times) material violation against cGMP).

In the event, that

(i) BI RCV AFFILIATE can not qualify as a second source manufacturer for PRODUCT or
(ii) in the event such a BI RCV AFFILIATE is – as foreseeable – unable to supply VIDARA’s PRODUCT requirements and

(iii) provided that PRODUCT supply as requested by VIDARA by a different second source manufacturer, a company experienced in manufacturing of biopharmaceuticals derived from ***, and selected by VIDARA could demonstrably take place earlier than a MATERIAL SUPPLY BREACH by BI RCV could be remedied, BI RCV shall assist VIDARA as requested in transferring the MANUFACTURING PROCESS to such a second source supplier, to be selected by VIDARA by providing, reasonable technical assistance and documentation relating to the manufacture, testing and supply of BBS and the PRODUCT as necessary at BI RCV’s cost. Such second source manufacturer would bear responsibility for putting the MANUFACTURING PROCESS in place. The total financial commitment for reasonable technical assistance shall not exceed ***

3.7.2 In the event that BI RCV reasonably anticipates that there is a substantial likelihood that a MATERIAL SUPPLY BREACH will occur, BI RCV shall promptly notify VIDARA in writing thereof. Upon receipt of such notice, the Parties shall promptly confer to discuss the circumstances and magnitude of such potential MATERIAL SUPPLY BREACH, and to determine in good faith whether there are any reasonable steps that BI RCV could take to avoid such MATERIAL SUPPLY BREACH. If VIDARA is not reasonably satisfied that BI RCV will be able to avoid such MATERIAL SUPPLY BREACH, then VIDARA shall forward this issue to the STEERING COMMITTEE to determine whether it is necessary or desirable to establish a second source manufacturer in accordance with Section 3.6.

4. PRICES AND PAYMENT

4.1 The prices to be paid by VIDARA for the PRODUCT provided hereunder have been agreed to by the Parties. Initially, the price of PRODUCT for market supply a unit of *** of PRODUCT and the price of one single vial of PRODUCT for clinical supply shall be in accordance with the prices in the table below and in accordance with the annual Rolling Forecast provided by VIDARA.

| *** | *** | *** |
| *** | *** | *** |
| *** | *** | *** |
| *** | *** | *** |
| *** | *** | *** |
| *** | *** | *** |
| *** | *** | *** |
| *** | *** | *** |

Commencing in ***, the price for the PRODUCT will be adjusted year by year in accordance with ***

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Payments by VIDARA to BI RCV under this AGREEMENT shall be in EUROS.

4.2 *** will be *** which are *** at the time such ***. BI RCV shall only purchase and maintain at any given time such quantities of COMPONENTS as reasonably necessary to manufacture and supply the PRODUCT to VIDARA in accordance VIDARA's forecast and this AGREEMENT and shall use reasonable efforts to maintain the level of inventory of COMPONENTS *** shall be entitled *** selected by *** which *** on verification concerning *** with *** days' notice of any ***.

4.3 BI RCV shall submit to VIDARA appropriate invoices for the price of the PRODUCT and any fees for services agreed upon by the Parties; provided, however, that with respect to the price of the PRODUCT, BI RCV shall submit invoices therefore only upon *** PRODUCT by BI RCV according to Section 3.4.1. The price for PRODUCT or any services agreed by the Parties shall be paid to BI RCV no later than *** days after the date that BI RCV's invoice is received by VIDARA. Payment of the invoice amounts shall be made in Austria, *** , into an account with such Austrian credit institution as shall be notified by BI RCV to VIDARA from time to time.

4.4 All payments owed to BI RCV by VIDARA on the basis of accounts rendered shall be made in such a way that *** shall *** on such ***. In the event of a default in payment for whatever reason, default interest at a rate of *** p.a. shall be payable on the outstanding amount due. BI RCV reserves the right to claim any damage exceeding such amount that shall have been caused by such delay, subject to Section 11.1.

5. QUALITY ASSURANCE AND COMPLIANCE WITH LAW

5.1 Quality Agreement. Simultaneously with the execution of this Agreement, or prior to such execution, the Parties shall execute the QUALITY AGREEMENT. Such QUALITY AGREEMENT is hereby incorporated by reference herein and that it shall apply to any BBS and PRODUCT produced under this Agreement. The QUALITY AGREEMENT shall in no way determine liability or financial responsibility of the Parties for the responsibilities set forth therein. In the event of a conflict between any of the provisions of this Agreement and the QUALITY AGREEMENT, the provisions of this Agreement shall prevail. The QUALITY AGREEMENT may be amended from time to time by the Parties only in accordance with Section 14.9.

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5.2 Manufacturing Facilities

BI RCV represents and warrants that it and BI Pharma KG shall obtain all relevant APPROVALS required by the relevant HEALTH AUTHORITIES for each of their respective manufacturing facilities and that each of their respective manufacturing facilities conform, and will during the term of this AGREEMENT conform, to the cGMP.

5.3 Compliance with Law

5.3.1 BI RCV shall comply, and shall ensure that its subcontractor BI Pharma KG shall comply with, all local applicable rules, laws and regulations (including without limitation cGMP) in performing its obligations under this AGREEMENT. VIDARA shall comply with all applicable rules, laws and regulations in performing its obligations under this AGREEMENT.

5.3.2 All costs in connection with maintaining BI RCV’s and BI Pharma KG’s compliance with all applicable local regulatory requirements and cGMP in performing under this AGREEMENT, including but not limited to the maintenance and upgrading of all technical facilities and infrastructure and the training of personnel, shall be borne by BI RCV. BI RCV shall obtain and maintain, and shall ensure that BI Pharma KG obtains and maintains, all permits and licenses necessary to its performance under this AGREEMENT at their own expense. All costs in connection with any requirements by VIDARA or a HEALTH AUTHORITY which relate specifically and solely to the PRODUCT (and not also to the BI PRODUCT) shall be solely borne by VIDARA. All costs in connection with any requirements by a HEALTH AUTHORITY which relate to the PRODUCT and the BI PRODUCT shall be equally borne by VIDARA and BI RCV. For purposes of clarity, all costs in connection with any requirements by BI RCV or a regulatory authority having jurisdiction over the manufacture, use and/or sale of the BI PRODUCT which relate specifically and solely to the BI PRODUCT (and not also to the PRODUCT) shall be solely borne by BI RCV.

5.3.3 If a Health Authority requests or requires that a change be made to the PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS, then BI RCV shall make such changes in accordance with the QUALITY AGREEMENT and SOPs (i.e., change control procedures) agreed in writing by VIDARA and BI RCV. Those changes are subject to written approval of each Party, which approval shall not be unreasonably withheld or delayed. In case that a request from a Health Authority may be challenged by either Party, VIDARA and/or BI RCV shall use commercially reasonable efforts to challenge the Health Authority on its decision and shall assist each other in its communication with the pertinent Health Authority requesting such a change. The costs for such a change shall be allocated between the Parties according to Section 5.3.2.

5.3.4 If VIDARA desires (for any reason other than a request or requirement by a Health Authority), to change the PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS, which relate specifically and solely to the PRODUCT (and not also to the BI PRODUCT), then BI RCV shall use reasonable commercial efforts to accommodate such request, subject to the following:
5.3.4.1 VIDARA shall promptly advise BI RCV and/or BI PHARMA KG in writing of any such change(s), and provide information necessary for BI RCV and/or BI PHARMA KG to evaluate the effect of such change(s). BI RCV shall promptly advise VIDARA as to scheduling changes, if any, which may result from such change(s). The notification and approval procedure shall be in accordance with standard operating procedures (i.e. change control procedures) agreed by the Parties from time to time, as described in the QUALITY AGREEMENT. The Parties shall hold a meeting in a timely manner to discuss such changes as appropriate.

5.3.4.2 Prior to implementation of any change(s), BI RCV shall provide VIDARA with a quote of the price of the services (which price shall be reasonable in nature and consistent with industry standards) and COMPONENTS that will be provided and purchased by BI RCV in order to implement any such change(s) to the PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS, including, but not limited to, the price of BI RCV’s validation and analytical services. If such changes will be implemented, then VIDARA shall pay the price of the services and COMPONENTS described in this Section.

5.3.4.3 BI RCV shall make changes or cause BI PHARMA KG to make these changes as described in this Section in accordance with timelines agreed to by the Parties, except that BI RCV and/or BI PHARMA KG shall have no obligation to make any such change where doing so, (i) in BI RCV’s reasonable judgment after due consultation with legal counsel having experience in such matters, which shall be communicated in writing to VIDARA, would violate any applicable law or regulations, or (ii) has a material adverse effect upon any regulatory filings for other BI RCV or BI PHARMA KG’s products, or (iii) would be incompatible with BI RCV’s and/or BI PHARMA KG’s established operations for biopharmaceuticals. For all changes requested by VIDARA, BI RCV shall cooperate with VIDARA in good faith to implement all agreed upon changes to PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS in accordance with the timelines agreed to by the Parties according to this Section 5.3.4.3.

5.3.5 VIDARA acknowledges and agrees that the Parties must agree in advance as of which point in time and to which manufacture of batches of PRODUCT changes to the PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS apply. However, VIDARA acknowledges and agrees that changes to the PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS during an ongoing campaign are not possible.

5.3.6 If any changes to the PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS render obsolete or unusable any COMPONENTS and if and to the extent those COMPONENTS may not be returned to the appropriate vendor for a credit, BI RCV and/or BI PHARMA KG, as applicable, shall either destroy or deliver to VIDARA, at VIDARA sole option, those obsolete or unusable COMPONENTS. VIDARA shall reimburse BI RCV for the costs of such COMPONENTS destroyed or provided to VIDARA to the extent the amount of COMPONENTS that would have been reasonably required for DI RCV and/or BI PHARMA KG to maintain in inventory in order to meet its obligations under this Agreement (consistent with its obligations under Section 4.2 hereof with respect to the COMPONENTS).

5.3.7 VIDARA may request additional regulatory services support from BI RCV (e.g., those set forth in Sections 2.1.2.1 and 2.2) with respect to the PRODUCT, in support of either obtaining or maintaining regulatory approval in any country of the TERRITORY. In such event,
BI RCV shall provide a quote of the price of such services (which pricing shall be reasonable in nature and consistent with industry standards), and shall provide such additional regulatory services upon mutual agreement on the scope and price of such services. For purposes of clarity and notwithstanding anything to the contrary contained in this Agreement, for purposes of maintaining regulatory approvals existing as of the EFFECTIVE DATE of this Agreement in any country of the TERRITORY, BI RCV will draw up the annual report required by the HEALTH AUTHORITIES pursuant to Section 2.1.2.3, assist in routine regulatory inspection with HEALTH AUTHORITIES and conduct annual stability studies without additional cost or expense to VIDARA. VIDARA will inform BI RCV in due time which regulatory support is requested from BI RCV.

5.4 Environmental

BI RCV shall, and shall ensure that BI Pharma KG shall, properly dispose of any and all hazardous waste materials involved with the manufacture of BBS and PRODUCT that are generated or resulting from the activities performed hereunder, if any, in full compliance with all applicable local laws and regulations at BI RCV’s sole liability and expense.

6. CO-OPERATION AND CO-ORDINATION BETWEEN THE PARTIES

6.1 Project Team

6.1.1 The day-to-day responsibilities of the Parties with respect to this AGREEMENT shall be overseen by the PROJECT TEAM, which shall be responsible for deciding operational and scientific issues arising out of this AGREEMENT and unanimously agreeing in good faith with respect to the monitoring of the compliance with this AGREEMENT.

6.1.2 The PROJECT TEAM shall consist of a team consisting of equal numbers of people, if feasible, each appointed by VIDARA and BI RCV and notified to the other, which appointees may be changed from time to time by the appointing Party on written notice to the other Party. Each member of the PROJECT TEAM shall be a person of appropriate skill and experience. Either Party may change its own designated PROJECT TEAM members provided, however that the total number of members of the PROJECT TEAM may not be changed if feasible, nor the number of members representing VIDARA decreased, without the Parties’ prior written agreement. VIDARA’s and BI RCV’s respective members of the PROJECT TEAM as of the Effective Date are listed in Exhibit 7.

6.1.3 During the term of this AGREEMENT, the PROJECT TEAM shall meet regularly to communicate updates and provide a forum for decision-making and rapid resolution of issues arising under this AGREEMENT. Meetings of the PROJECT TEAM may be conducted by telephone conference, videoconference or face-to-face meetings as agreed by the PROJECT TEAM.

6.1.4 Decisions of the PROJECT TEAM shall be reflected in the approved minutes. Meeting minutes shall be prepared jointly by the PROJECT MANAGERS to record all issues discussed and decisions. Minutes that have not been objected to in writing by a Party within six (6) business days of receipt thereof shall be deemed approved by such Party and followed by issuance of the minutes duly executed by the Parties’ PROJECT MANAGER.
6.1.5 In the event that the PROJECT TEAM is unable to reach agreement on any issue and is unable to make decisions arising out of operational and scientific issues within ten (10) business days, each Party may call in an expert of its own choice to render advice to the PROJECT TEAM. Based on the advice of such expert(s) and the team members’ know-how, the PROJECT TEAM will try to resolve such issue. In the event that the PROJECT TEAM fails to reach agreement on an issue within thirty (30) business days of first undertaking resolution of such issue, such issue shall then be referred to the STEERING COMMITTEE for immediate resolution.

6.2 Steering Committee

6.2.1 The Parties shall create a STEERING COMMITTEE consisting of the PROJECT MANAGER of each Party and authorized representatives who shall be appointed by VIDARA and by BI RCV in equal numbers, if feasible, and notified to the other Party. The STEERING COMMITTEE shall be responsible for unanimously agreeing in good faith all issues on which the PROJECT TEAM has been unable to reach agreement and, where possible, make decisions arising out of such issues as well as carry out the specific functions, including but not limited to decisions with an impact on costs and timelines of any activities to be carried out under this AGREEMENT. Each Party may change its own designated STEERING COMMITTEE members by providing written notice thereof to the other Party, provided, however that the total number of members of the STEERING COMMITTEE may not be changed, if feasible, nor the number of members representing VIDARA decreased, without the Parties’ prior written agreement. The members of the STEERING COMMITTEE are listed in Exhibit 9.

6.2.2 The STEERING COMMITTEE shall attempt in good faith to expeditiously and fairly resolve all issues before it. In the event that the STEERING COMMITTEE is unable to resolve any issue before it within fifteen (15) business days from the date that such issue is referred to it, such issue shall be referred to the Chief Executive Officer of VIDARA and the Chief Executive Officer of BI RCV for prompt, good faith resolution. If such individuals do not reach agreement on such issue within fifteen (15) days of such referral, then each Party shall be free to pursue all available legal and/or equitable remedies.

6.3 Limitation of Powers

The powers of the PROJECT TEAM and the STEERING COMMITTEE are limited to those expressly set forth in this AGREEMENT. Without limiting the generality of the foregoing, neither the PROJECT TEAM nor the STEERING COMMITTEE shall have the right to amend this AGREEMENT. The actions of the PROJECT TEAM and/or the STEERING COMMITTEE shall not substitute for either Party’s ability to exercise any right, nor excuse the performance of any obligation, set forth herein.

7. INTELLECTUAL PROPERTY AND LICENSES

7.1 The ownership of VIDARA’S TECHNOLOGY and shall remain with VIDARA and shall not vest in BI RCV.

7.2 The ownership of BI RCV’S TECHNOLOGY shall remain with BI RCV and shall not vest in VIDARA.
7.3 BI RCV shall retain ownership of BI RCV’S IMPROVEMENTS. BI RCV hereby grants to VIDARA a non-exclusive, perpetual, sublicensable, royalty free license under BI RCV’S IMPROVEMENTS (i) to the extent necessary to develop, use, import, offer for sale and sell products containing INTERFERON GAMMA 1b in the name and on the account of VIDARA in the TERRITORY, and (ii) in the event VIDARA transfer the process to a second source manufacturer as permitted under this AGREEMENT, to make and have made products containing INTERFERON GAMMA 1b in the name and on account of VIDARA in the TERRITORY, whereby in each case VIDARA shall assume the costs to be paid by BI RCV for awards to inventors of BI RCV’S IMPROVEMENTS, as such awards are set forth in written agreements between BI RCV and such inventor or in an applicable industry labor contract or mandatory by Austrian laws.

7.4 The Parties shall each have an undivided one-half ownership interest in any INFORMATION jointly conceived of or reduced to practice by the Parties pursuant to the ORIGINAL SUPPLY AGREEMENT, the RESTATED SUPPLY AGREEMENT, the AMENDED AND RESTATED AGREEMENT and/or this AGREEMENT (“JOINT INFORMATION”). VIDARA shall *** of any JOINT INFORMATION that comprises (a) any regulatory filing (or documentation and raw data relating thereto) relating to PRODUCT manufactured hereunder or the ORIGINAL SUPPLY AGREEMENT, the RESTATED SUPPLY AGREEMENT or the AMENDED AND RESTATED AGREEMENT, or (b) any manufacturing documentation (including without limitation batch records) relating to PRODUCT manufactured hereunder or the ORIGINAL SUPPLY AGREEMENT, the RESTATED SUPPLY AGREEMENT or the AMENDED AND RESTATED AGREEMENT (“PRODUCT INFORMATION”). Upon request by VIDARA, without additional consideration, BI RCV agrees to promptly execute documents, testify and take other acts at VIDARA’s expense as VIDARA may deem necessary or desirable to procure, maintain, perfect, and enforce the full benefits, enjoyment, rights, title and interest of the PRODUCT INFORMATION, on a worldwide basis. In the event VIDARA is unable for any reason, after reasonable effort, to secure BI RCV’s signature on any document needed in connection with the actions specified in this Section 7.4, BI RCV hereby irrevocably designates and appoints VIDARA and its duly authorised officers and agents as its agent and attorney in fact, which appointment is coupled with an interest, to act for and in its behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of this Section 7.4 with the same legal force and effect as if executed by BI RCV.

7.5 VIDARA hereby grants to BI RCV (with the right to sublicense solely to BI Pharma KG) a non-exclusive, nontransferable license to use VIDARA’S TECHNOLOGY solely for the purpose of manufacturing PRODUCT for VIDARA, as provided in this AGREEMENT. The license granted under this Section shall automatically terminate upon the expiration or termination of this AGREEMENT.

7.6 New Indications

7.6.1 In the event that VIDARA receives approval in the TERRITORY to commercially sell PRODUCT for indications other than **Chronic Granulomatous Disease** and **severe, malignant Osteopetrosis**, and provided that VIDARA has the right to grant a license to BII in the BI

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
TERRITORY to make, use and sell PRODUCT for such additional indications (a “NEW INDICATIONS LICENSE”), VIDARA shall provide BII written notice thereof.

7.6.2 BII shall notify VIDARA in writing within thirty (30) days of VIDARA’s notice (the “NOTIFICATION PERIOD”) whether BII desires to obtain a NEW INDICATIONS LICENSE. If VIDARA does not receive written notice from BII during the NOTIFICATION PERIOD that BII desires to obtain a NEW INDICATIONS LICENSE, then VIDARA shall have no further obligations under this Section 7.6. If VIDARA does receive written notice from BII that BII desires to obtain a NEW INDICATIONS LICENSE, then BII and VIDARA shall engage in good faith negotiations for sixty (60) business days thereafter regarding the reasonable commercial terms upon which VIDARA would be willing to grant such a license. If at the end of such sixty (60) business day period, BII and VIDARA have not entered into a written agreement under which VIDARA grants a NEW INDICATIONS LICENSE to BII, then VIDARA shall have no further obligation under this Section 7.6.

8. COMPLAINTS; ADVERSE EVENTS; RECALLS

8.1 VIDARA shall inform BI RCV of any complaints, adverse reaction reports, safety issues or toxicity issues relating to any PRODUCT of which it becomes aware, regardless of the origin of such information, pursuant to the terms set forth in the QUALITY AGREEMENT.

8.1.1 VIDARA shall retain and manage complaints in accordance with cGMP. The Parties hereby agree to cooperate with one another and with any HEALTH AUTHORITY in the evaluation and investigation of any complaint, claim or adverse reaction report related to the manufacture of such PRODUCT with the intention of complying with cGMP.

8.1.2 If any such event occurs, BI RCV shall retain any unused supplies of such PRODUCT and its associated components, and all associated batch and other production records in such manner as VIDARA may reasonably direct, and at VIDARA’s expense, except to the extent such event is caused by BI RCV’s wrongful act or omission. BI RCV agrees to respond to VIDARA in respect to such complaint investigations involving BI RCV’s manufacturing of a PRODUCT hereunder as soon as reasonably possible but in any case within thirty (30) days from receipt by BI RCV of the report of such complaint and sample (if available), or in the case of a serious adverse event, within ten (10) days from receipt of the report of such complaint and sample (if available). VIDARA and/or its designee shall serve as the sole point of contact with the FDA or other applicable HEALTH AUTHORITY concerning any complaints, adverse reaction reports, safety issues or toxicity issues with respect to PRODUCT.

8.2 If either Party becomes aware at any time of any defect or the possibility of any defect associated with any PRODUCT manufactured by BI RCV hereunder, such Party will notify the other Party immediately and confirm the notification within two (2) days in writing.

8.3 VIDARA shall notify BI RCV within one (1) day if any PRODUCT manufactured by BI RCV hereunder is the subject of a recall, market withdrawal or correction, and VIDARA and/or its designee shall have the sole responsibility for the handling and disposition of such recall, market withdrawal or correction. In the event that a recall is required in connection with BI RCV’s breach of any of its warranties set forth in Section 9.2 hereof, BI RCV shall reimburse
VIDARA for the purchase price of such PRODUCT and all other reasonable costs and expenses associated with such PRODUCT recall, market withdrawal or correction, but only to the extent that the foregoing costs and expenses are attributable to BI RCV’s breach of its warranties hereunder. In all other events of a recall, all costs and expenses incurred in connection with such PRODUCT recall shall be borne by VIDARA. VIDARA and/or its designee shall serve as the sole point of contact with the FDA or other applicable HEALTH AUTHORITY concerning any recall, market withdrawal or correction with respect to the PRODUCT.

8.4 Insurance

During the term of this AGREEMENT, the Parties shall maintain product liability insurance in such amounts and with such scope of coverage as are adequate to cover the Parties’ obligations under this AGREEMENT and as appropriate for companies of like size, taking into account the scope of activities contemplated herein. Notwithstanding the foregoing the Parties shall maintain minimum limits of product liability of *** US$ per occurrence and in the aggregate annually. The Parties shall provide to each other within ten (10) business days of execution of this AGREEMENT and thereafter, once a year upon the other Party’s request, a certificate of insurance evidencing the respective Party’s product liability insurance. In addition to the foregoing coverage, the Parties shall maintain Comprehensive General Liability Insurance for limits of not less than *** US$ per occurrence and in the aggregate annually for bodily injury and property damage.

9. REPRESENTATIONS AND WARRANTIES

9.1 Each Party hereby represents and warrants to the other Party that: (a) the person executing this AGREEMENT is authorized to execute this AGREEMENT; (b) this AGREEMENT is legal and valid and the obligations binding upon such Party are enforceable by their terms; and (c) the execution, delivery and performance of this AGREEMENT does not conflict with any agreement, instrument or understanding, oral or written, to which such Party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

9.2 BI RCV represents and warrants that:

9.2.1 All BBS manufactured hereunder shall conform to BULK SPECIFICATIONS;

9.2.2 All PRODUCT manufactured and supplied hereunder shall – at the date of shipment – conform to the PRODUCT SPECIFICATIONS;

9.2.3 All BBS and PRODUCT manufactured and supplied hereunder shall be manufactured in accordance with the MANUFACTURING PROCESS;

9.2.4 All BBS and PRODUCT manufactured hereunder shall be manufactured, handled, stored, labeled, packaged and transported (from BI RCV to BI Pharma KG) in accordance with the cGMP requirements, the QUALITY ASSURANCE REQUIREMENTS as set forth in the QUALITY AGREEMENT and all applicable laws, regulations and ordinances of the jurisdiction in which such manufacture occurs.

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
9.2.5 No PRODUCT manufactured and supplied to VIDARA hereunder shall be (i) adulterated or misbranded by BI RCV within the meaning of the FD&C Act, or (ii) an article that may not be introduced into interstate commerce under the provisions of Sections 404 or 505 of the FD&C Act; and

9.2.6 BI RCV shall not use and shall secure that BI Pharma KG shall not use in any capacity the services of any persons debarred under 21 U.S.C. sections 335 (a) and 335 (b) in connection with the manufacture of the PRODUCT under this AGREEMENT.

9.3 Except as expressly provided for herein, BI RCV makes no further warranties of the merchantability or fitness of the PRODUCT or any warranties of any other nature, express or implied.

10. INDEMNIFICATION

10.1 Subject to Section 10.3, BI RCV shall indemnify, defend and hold harmless VIDARA and its officers, directors, employees and agents from and against all third party costs, claims, (including death and bodily injury) suits, expenses (including reasonable attorneys’ fees), liabilities and damages (collectively, “LIABILITIES”) arising out of or resulting from any willful or negligent act or omission by BI RCV or BI Pharma KG relating to the subject matter of this AGREEMENT, or any defect in the manufacture or any failure to deliver PRODUCT in accordance with BI RCV’s warranties (except to the extent such LIABILITIES arose or resulted from any negligent act or omission by VIDARA).

10.2 Subject to Section 10.3, VIDARA shall indemnify, defend and hold harmless BI RCV and its officers, directors, employees and agents from and against all LIABILITIES arising out of or resulting from any willful or negligent act or omission by VIDARA relating to the subject matter of this AGREEMENT, or the use by or administration to any person of a PRODUCT manufactured by BI RCV in performance of its obligations under this AGREEMENT (except to the extent such LIABILITIES arose or resulted from any negligent act or omission by BI RCV or BI Pharma KG or any defect in the manufacture of PRODUCT or any failure to deliver PRODUCT in accordance with BI RCV’s warranties).

10.3 A Party and its directors, officers, employees and agents which intends to claim indemnification under this Article 10 (each, an “INDEMNITEE”) shall promptly notify the other Party (the “INDEMNITOR”) in writing of any action, claim or other matter in respect of which the INDEMNITEE intend to claim such indemnification; provided, however, that the failure to provide such notice within a reasonable period of time shall not relieve the INDEMNITOR of any of its obligations hereunder except to the extent that the INDEMNITOR is prejudiced by such failure. The INDEMNITEE shall permit the INDEMNITOR at its discretion to settle any such action, claim or other matter, and the INDEMNITEE agrees to the complete control of such defense or settlement by the INDEMNITOR. Notwithstanding the foregoing, the INDEMNITOR shall not enter into any settlement that would adversely affect the INDEMNITEE’s rights hereunder, or impose any obligations on the INDEMNITEE in addition to those set forth herein in order for it to exercise such rights, without INDEMNITEE’s prior written consent, which shall not be unreasonably withheld or delayed. No such action, claim or other matter shall be settled without the prior written consent of the INDEMNITOR, which shall
not be unreasonably withheld or delayed. The INDEMNITOR shall not be responsible for any attorneys' fees or other costs incurred other than as provided herein. The INDEMNITEE shall cooperate fully with the INDEMNITOR and its legal representatives in the investigation and defense of any action, claim or other matter covered by the indemnification obligations of this Article 10. The INDEMNITEE shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection and at its own expense.

11. LIMITATIONS ON LIABILITY

11.1 In no event shall either Party be liable to the other Party for any consequential, incidental, special or indirect damages arising in connection with this AGREEMENT except in the case of willful misconduct or omission by such Party.

11.2 Except as set forth in the following sentence, BI RCV’s total liability under this Agreement shall not exceed ***. However, with respect to BI RCV’s indemnification obligations under Article 10, BI RCV’s total liability shall not exceed *** per occurrence of an act or omission by BI RCV giving rise to a claim for indemnification by VIDARA against BI RCV under Article 10, except in the event of BI RCV’s willful misconduct.

12. CONFIDENTIALITY

12.1 Each Party shall treat confidentially all CONFIDENTIAL INFORMATION of the other Party, and shall not use or disclose such CONFIDENTIAL INFORMATION other than it is expressly permitted under this AGREEMENT. Each Party will take steps to protect the other Party’s CONFIDENTIAL INFORMATION that are at least as stringent as the steps such Party uses to protect its own CONFIDENTIAL INFORMATION, but in no event shall be less than reasonable. Each Party may disclose the other Party’s CONFIDENTIAL INFORMATION to employees, contractors and agents who are bound by written obligations of confidentiality and non-use consistent with those set forth in this AGREEMENT. BI RCV may disclose CONFIDENTIAL INFORMATION for corporate reporting purposes to its AFFILIATES BI Pharma KG and Boehringer Ingelheim GmbH.

12.2 Each Party may disclose Confidential Information of the other Party hereunder to the extent that such disclosure is reasonably necessary for prosecuting or defending litigation, complying with applicable government regulations, conducting preclinical or clinical trials or obtaining marketing approval for the PRODUCT, provided that if a Party is required by law or regulation to make any such disclosure of the other Party’s CONFIDENTIAL INFORMATION it will, except where impracticable for necessary disclosures, for example in the event of medical emergency, give reasonable advance notice to the other Party of such disclosure requirement and will use its best efforts assist such other Party to secure a protective order or confidential treatment of such CONFIDENTIAL INFORMATION required to be disclosed.

12.3 Neither Party shall disclose CONFIDENTIAL INFORMATION of the other Party in any patent filings without the prior written consent of such other Party.

12.4 The Parties agree that, except as may otherwise be required by applicable laws, regulations, rules, or orders, including without limitation the rules and regulations promulgated

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by the US Securities and Exchange Commission, and except as may be authorised in Section 12.2, no material information concerning this AGREEMENT and the transactions contemplated herein shall be made public by either Party without the prior written consent of the other. The Parties agree that the public announcement of the execution of this AGREEMENT shall be by one or more press releases mutually agreed to by the Parties. A failure of a Party to return a draft of a press release with its proposed amendments or modifications to such press release to the other Party within five (5) business days of such Party’s receipt of such press release shall be deemed as such Party’s approval of such press release as received by such Party. Each Party agrees that it shall cooperate fully and in a timely manner with the other with respect to all disclosures to the Securities and Exchange Commission and any other governmental and regulatory agencies, including requests for confidential treatment of CONFIDENTIAL INFORMATION of either Party included in any such disclosure.

12.5 This confidentiality obligations of this Article 12 shall survive the termination or expiration of this AGREEMENT for a period of five (5) years.

13. DURATION AND TERMINATION

13.1 Duration
The AGREEMENT shall be effective as of the Effective Date and shall continue in force until 31 July, 2020. No later than *** prior to the expiration of this AGREEMENT, the Parties shall discuss and determine whether the term of the AGREEMENT shall be extended by the Parties. In the event the Parties mutually determine that the term of the AGREEMENT should be extended, the Parties shall enter into an amendment to this AGREEMENT to effectuate such an extension. Where the Parties have so mutually determined to extend the term of the AGREEMENT as provided herein, but are subsequently unable following good faith negotiation to agree on the terms of an amendment, then the term of this AGREEMENT shall end on 31 July, 2020 or *** from the date the Parties mutually agree to cease negotiations of an extension, whichever occurs later.

13.2 Early Termination
13.2.1 In the event that a Party materially breaches its obligations under this AGREEMENT (including without limitation a MATERIAL SUPPLY BREACH and a late payment of more than thirty (30) days), the non-breaching Party may terminate this AGREEMENT upon thirty (30) days prior written notice to the breaching Party, unless the breaching Party cures such breach to the non-breaching Party’s reasonable satisfaction during such thirty day period. Notwithstanding the preceding sentence, in the event that a Party materially breaches its obligations under this AGREEMENT more than two (2) times in any consecutive twenty-four (24) month period, the non-breaching Party may terminate this AGREEMENT immediately without providing the breaching Party an opportunity to cure such breach, by giving the breaching Party written notice thereof.

13.2.2 Each Party may terminate this AGREEMENT by notice in writing to the other Party, for cause, if such other Party is adjudicated to be insolvent or files a petition in bankruptcy.

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.

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13.2.3 VIDARA may immediately terminate this AGREEMENT by notice in writing if VIDARA should be prevented by the HEALTH AUTHORITIES from distributing PRODUCT on the market for all indications. In such event, *** for the following: (A) VIDARA shall either (at VIDARA’s discretion) (i) *** in accordance with the then existing *** under the *** (in which case *** or (ii) *** of the unit price of the PRODUCT then in effect for the PRODUCT forecasted in the then existing *** under the *** ; and (B) *** of any non-cancelable costs incurred by BI RCV for COMPONENTS which were purchased by BI RCV at VIDARA’s request to the extent that VIDARA has not yet paid for such COMPONENTS; provided that VIDARA shall have no liability to BI RCV under this Section 13.2.3 in the event that such HEALTH AUTHORITY action is solely due to any breach of BI RCV’s warranties under this Agreement or any negligence or willful misconduct by BI RCV or BI Pharma KG.

13.2.4 All payments in connection with early termination shall be due within thirty (30) days after receipt by BI RCV of the notice of early termination from VIDARA and receipt by VIDARA of the respective invoice from BI RCV.

13.3 Effect of Termination

13.3.1 In the event of any termination of this AGREEMENT (other than for BI RCV’s material breach or negligence or willful misconduct by BI RCV or BI Pharma KG), VIDARA shall also do one of the following (at VIDARA’s option): (i) VIDARA shall purchase (in which case BI RCV shall sell) PRODUCT *** to *** of the unit price of the PRODUCT then in effect for the PRODUCT *** provided, however, that with regard to any *** by BI RCV (or BI Pharma KG, as the case may be) at the time of termination, ***. Notwithstanding the foregoing, in the event of termination by VIDARA under Section 13.2.3, Section 13.2.3 shall govern rather than this Section 13.3.1.

13.3.2 In the event of any termination or expiration of this AGREEMENT, at the request of VIDARA, BI RCV shall either (i) destroy all material, including but not limited to samples and all documentation received from VIDARA under this AGREEMENT, the ORIGINAL SUPPLY AGREEMENT and the RESTATED SUPPLY AGREEMENT, or (ii) deliver the same to VIDARA or a party nominated by VIDARA, at VIDARA’s cost (except in the case of termination by VIDARA for BI RCV’s material breach, in which case such destruction or delivery shall be at BI RCV’s expense).

13.3.3 BI RCV shall promptly return all of VIDARA’s CONFIDENTIAL INFORMATION (as well as all CONFIDENTIAL INFORMATION of VIDARA provided to BI RCV under the ORIGINAL SUPPLY AGREEMENT and the RESTATED SUPPLY AGREEMENT) to VIDARA, except for a single copy and/or sample of each item for documentation purposes only. BI RCV’s responsibility to keep and store all other materials provided by VIDARA in the course of this AGREEMENT shall terminate six (6) months after expiration or termination of this

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
13.3.4 VIDARA shall promptly return all of BI RCV’s CONFIDENTIAL INFORMATION (as well as all CONFIDENTIAL INFORMATION of BI RCV provided to VIDARA under the ORIGINAL SUPPLY AGREEMENT and the RESTATED SUPPLY AGREEMENT) to BI RCV, except for a single copy and/or sample for documentation purposes only.

13.3.5 The following provisions shall survive termination of this AGREEMENT: Sections 3.7.1, 7.1, 7.2, 7.3, 7.4, 7.5, 8, 10, 11, 12, 13.2.3, 13.2.4, 13.3 and 14. In addition, the applicable terms of the QUALITY AGREEMENT with respect to the storage of records and batch samples for each batch of PRODUCT shall also survive the termination of this AGREEMENT. Termination of this AGREEMENT shall not relieve either Party of any liability which accrued hereunder prior to the effective date of such termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this AGREEMENT, nor prejudice either Party’s right to obtain performance of any obligation.

14. MISCELLANEOUS

14.1 Performance by Affiliates

The Parties recognize that each Party may perform some or all of its obligations under this AGREEMENT through one or more of its AFFILIATES, provided, however, that each Party shall remain responsible for such performance by its AFFILIATES and shall cause its AFFILIATES to comply with the provisions of this AGREEMENT in connection with such performance. Each Party hereby expressly waives any requirement that the other Party exhausts any right, power or remedy, or proceeds against an AFFILIATE, for any obligation or performance hereunder prior to proceeding directly against such Party.

14.2 Force Majeure

Neither Party shall be liable for any failure or delay in performance or non-performance caused by circumstances beyond the reasonable control of such Party, including but not limited to acts of God, explosion, fire, flood, labor strike or labor disturbances, sabotage, order or decree of any court or action of any governmental authority (except where such order, decree or action is a direct result of BI RCV’s breach of its obligations hereunder), or other causes, whether similar or dissimilar to those specified which cannot reasonably be controlled by the Party who failed to perform (each such event, a “FORCE MAJEURE EVENT”). A Party affected by a FORCE MAJEURE EVENT shall give notice of such to the other Party as soon as is reasonably possible, and shall resume performance hereunder as soon as is reasonably possible. Each Party shall have the right to terminate this AGREEMENT in the event that a FORCE MAJEURE EVENT continues for more than thirty (30) business days upon written notice thereof.

14.3 Assignment

14.3.1 Except as expressly provided for herein neither this AGREEMENT nor any rights or obligations hereunder may be assigned by either Party without the other Party’s prior written consent (not to be unreasonably withheld or delayed), except that either Party may (a) assign its
rights and obligations under this Agreement to any of its AFFILIATES, or (b) assign this AGREEMENT in its entirety to its successor to all or substantially all of its business or assets to which this AGREEMENT relates, unless such successor does not have the financial resources to perform such Party’s obligations under this AGREEMENT in the reasonable judgment of the other Party by submitting pertinent financial information to such other Party. In the event of (b) above, BI RCV reserves the right to terminate the AGREEMENT in the event that such successor is a direct competitor to BI RCV in the field of contract manufacturing of biopharmaceuticals by means of yeast or microbial fermentation. In case of an assignment, the assigning party shall immediately notify the other Party about the intended or executed assignment, as applicable, and the assignee. Any subsequent assignee or transferee shall be bound by the terms of this AGREEMENT. Any assignment of this AGREEMENT that is not in conformance with this Section 14.3 shall be null, void and of no legal effect.

14.4 Notices

Any notice required or permitted to be given hereunder by either Party shall be in writing and shall be (i) delivered personally, (ii) sent by registered mail, return receipt requested, postage prepaid or (iii) delivered by facsimile and confirmed by certified or registered mail to the addresses or facsimile numbers set forth below:

If to VIDARA: VIDARA Therapeutics Research Ltd
Adelaide Chambers, Peter Street, Dublin 8, Ireland
Facsimile: +353 (0) 1449 3250
Attention: VP Business Development

If to BI RCV: Boehringer Ingelheim RCV GmbH & Co KG
Dr. Boehringer-Gasse 5 – 11
A-1121 Vienna, Republic of Austria
Facsimile: +43 – 1 – 801 05 - 2440
Attention:
VP Business Development & Key Account Mgmt Europe
Biopharmaceuticals, Contract Manufacturing Business

with a copy to: Boehringer Ingelheim GmbH
Binger Strasse 173
D-55 216 Ingelheim am Rhein
Facsimile: +49 – 61 32 77 – 98 287
Attention: Head of Corporate Legal Biopharmaceuticals

14.5 Dispute Resolution; Governing Law

14.5.1 In the event of any controversy or claim arising out of, relating to or in connection with any provision of this AGREEMENT, or the rights or obligations of the Parties hereunder, the Parties first shall try to settle their differences amicably between themselves by referring the disputed matter to the Chief Executive Officer of VIDARA and the Managing Director of BI RCV for discussion and resolution. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within ten (10) days of such notice.
the Chief Executive Officer of VIDARA and the Managing Director of BI RCV shall meet for attempted resolution by good faith negotiations. If such personnel are unable to resolve such dispute within thirty (30) days of initiating such negotiations, the controversy or claim will be referred to binding arbitration as set forth in Section 14.5.2.

**14.5.2** Any controversy or claim arising out of, relating to or in connection with any provision of this AGREEMENT, or the rights or obligations of the Parties hereunder, and not resolved by executive mediation in accordance with Section 14.5.1 hereof, shall be referred to and finally settled by binding arbitration, in accordance with the Rules of Arbitration of the International Chamber of Commerce in force on the date the demand for arbitration is filed, which Rules are deemed to be incorporated by reference into this clause. ***

. The language to be used in the arbitral proceedings shall be English. The place of arbitration shall be New York, New York (USA). Any determination by such arbitration shall be final and conclusively binding. Judgment on the arbitral award may be entered in any court having jurisdiction thereof. ***

**14.5.3** This AGREEMENT shall be governed by and construed in accordance with the laws of the state of New York (USA), without reference to its conflict of law rules.

**14.5.4** The Parties expressly exclude the application of the United Nations Convention on Contracts for the International Sale of Goods to this AGREEMENT.

**14.6 Independent Contractor**

Each of the Parties hereto is an independent contractor and nothing herein contained shall be deemed to constitute the relationship of partners, joint venture, nor of principal and agent between the Parties hereto. Neither Party shall have the authority to bind the other Party.

**14.7 Waiver**

Any delay in enforcing a Party’s rights under this AGREEMENT or any waiver as to a particular default or other matter shall not constitute a waiver of such Party’s rights to the future enforcement of its rights under this AGREEMENT, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

**14.8 Severability**

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
If any of the provisions of this AGREEMENT or parts thereof should be or become invalid, the remaining provisions will not be affected. The Parties shall undertake to replace the invalid provision or parts thereof by a new provision which will approximate as closely as possible the intent of the Parties.

14.9 Entire Agreement
This AGREEMENT, the QUALITY AGREEMENT, the TERMINATION AGREEMENT and the Exhibits set forth the entire agreement between the Parties, and supersede all previous agreements (including but not limited to the RESTATED SUPPLY AGREEMENT), negotiation and understanding, written or oral, regarding the subject matter hereof. This AGREEMENT may be modified or amended only by an instrument in writing duly executed on behalf of the Parties. For the avoidance of doubt, this AGREEMENT does not supersede the TERMINATION AGREEMENT entered into by the Parties on June 6, 2007.

14.10 Headings
The section headings appearing herein are included solely for convenience of reference and are not intended to affect the interpretation of any provision of this AGREEMENT.

14.11 Ambiguities
Ambiguities, if any, in this AGREEMENT shall not be strictly construed against either Party, regardless of which Party is deemed to have drafted the provision at issue.

14.12 Counterparts
The AGREEMENT may be executed in two or more counterparts, each of which shall be an original and all of which shall constitute the same document.

14.13 English Language
The English language will govern any interpretation of or dispute in connection with this AGREEMENT.
IN WITNESS WHEREOF, the Parties hereto have caused this AGREEMENT to be executed by their duly authorized representatives as of the EFFECTIVE DATE.

Vienna, Austria

**BOEHRINGER INGELHEIM RCV GMBH & CO KG**

By: /s/ Dr. Monika Henninger
Name: Dr. Monika Henninger
Title: VP Business Development & Key Account Management Europe
Date: 18 July 2013

By: /s/ Dr. Christian Eckermann
Name: Dr. Christian Eckermann
Title: Vice President Operations & Chair of Biopharma/Site Austria
Date: 22 July 2013

Dublin, Ireland

**Vidara Therapeutics Research, Ltd.**

By: /s/ David G. Kelly
Name: David G. Kelly
Title: Director & Chief Financial Officer
Date: 25th July, 2013
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EXHIBIT 1

BBS SPECIFICATIONS

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*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
Certificate of Analysis (COA):

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*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
EXHIBIT 3
SEE ATTACHED CERTIFICATE OF COMPLIANCE
DNA sequence of INTERFERON GAMMA 1b

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EXHIBIT 5
MANUFACTURING PROCESS

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*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
EXHIBIT 7

Project Manager and Project Team:
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*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
Product Specification

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*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
Steering Committee

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LICENSE AGREEMENT FOR INTERFERON GAMMA

This Agreement is entered into effective as of May 5, 1998, (“Effective Date”) by and between Connetics Corporation, a Delaware corporation with its principal office at 3400 West Bayshore Road, Palo Alto, California 94303 (“Connetics”), and Genentech, Inc., a Delaware corporation with its principal office at 1 DNA Way, South San Francisco, California 94080 (“Genentech”).

WHEREAS, Connetics wishes to obtain a non-exclusive license to manufacture and an exclusive license to use, sell, offer for sale and import Interferon Gamma (as defined herein) in the United States for the treatment of certain medical disorders;

WHEREAS, in consideration for the foregoing, Connetics will issue to Genentech shares of Connetics Common Stock on the terms and conditions set forth in that certain stock purchase agreement between Genentech and Connetics of even date herewith (the “Stock Agreement”);

WHEREAS, Genentech will manufacture and supply Connetics with Interferon Gamma-1B (as defined herein) under the terms and conditions set forth in that certain supply agreement between Genentech and Connetics of even date herewith (the “Supply Agreement”);

WHEREAS, Connetics and Genentech are parties to that certain Agreement on Interferon Gamma-1B dated December 8, 1995 (the “Prior Agreement”) and desire to terminate the Prior Agreement effective as of the date hereof and to accept the rights and
obligations created pursuant hereto in lieu of the rights and obligations under the Prior Agreement; and

WHEREAS, Genentech and Connetics therefore agree to undertake the foregoing, all under the terms and conditions set forth in this Agreement and for the consideration set forth herein and in the Stock Agreement.

NOW, THEREFORE, in consideration of the mutual promises contained herein, the Parties agree as follows:

1.0 Definitions

1.1 “Best Efforts” shall mean every necessary and prudent effort of a Party applied in a prompt, commercially reasonable manner, to the maximum extent reasonably allowed by such Party’s available financial resources, taking into account all of such Party’s business commitments for such financial resources.

1.2 “*** License” shall mean that certain license agreement between Genentech and *** dated January 5, 1990, as amended on November 23, 1992.

1.3 “*** License Rights” shall mean all sublicenseable rights granted to Genentech by *** under the *** License.

1.4 “BLA” shall mean Biologics License Application.

1.5 “Bulk Product” shall mean Interferon Gamma-1B provided as bulk protein manufactured in compliance with Good Manufacturing Practices, pursuant to applicable FDA regulatory approvals and supplied to Connetics in such a form and in such containers as shall be mutually determined by Genentech and Connetics and as described in the Supply Agreement.

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1.6 “C.F.R.” shall mean Code of Federal Regulations.

1.7 “CGD” shall mean chronic granulomatous disease.

1.8 “Connetics Knowhow” shall mean all proprietary information, methods, processes, techniques and data that have not been publicly disclosed, that relate to Interferon Gamma and that arise out of Connetics’ and its sublicensees’ efforts in the development of Interferon Gamma (including Interferon Gamma as part of a Licensed Product) hereunder and that on the Effective Date and hereafter during the term of this Agreement are owned or controlled by Connetics or its sublicensees or under which Connetics or its sublicensees otherwise has the right to grant licenses or sublicenses.

1.9 “Connetics Patent Rights” shall mean all patents, patent applications and any patents issuing therefrom, together with any substitutions, extensions, reexaminations, reissues, renewals, divisions, continuations and continuations-in-part thereof, that (a) claim inventions constituting Interferon Gamma or its manufacture or use that arise out of Connetics’ or its sublicensor’s efforts in the development of Interferon Gamma (including Interferon Gamma as part of a Licensed Product) hereunder during the term of this Agreement, and (b) are owned by Connetics or its sublicensees or under which Connetics or its sublicensees otherwise has the right to grant licenses or sublicenses as provided herein.

1.10 “ELA” shall mean Establishment License Application.

1.11 “FDA” shall mean the United States Food and Drug Administration.

1.12 “Field of Use” shall mean the administration to humans of Licensed Product for the treatment or prevention of: (a) any dermatological disease or condition including, without limitation, atopic dermatitis, keloids/hypertrophic scars, pustular psoriasis and scleroderma, but excluding any cancer disease or condition, (b) any infectious disease or
condition including, without limitation, fungal, viral and bacterial infections, (c) osteopetrosis, (d) chronic granulomatous disease, (e) pulmonary fibrosis, and (f) asthma. Notwithstanding the foregoing, the Field of Use shall not include the administration to humans of Licensed Product for the treatment or prevention of any type of arthritis or cardiac or cardiovascular disease or condition, or use of Licensed Product for any indication or use in the field of oncology or endocrinology. Each of Subsections 1.12 (a) through (f) inclusive shall hereinafter each be referred to individually as an “Area of the Field of Use” and together as the “Areas of the Field of Use.”

1.13 “Finished Product” shall mean Interferon Gamma-1B supplied in vialed form as 100 micrograms of Interferon Gamma-1B protein in a 0.5 ml fill volume and as described in the Supply Agreement, manufactured in compliance with Good Manufacturing Practices and intended for commercial sale to treat CGD and osteopetrosis and for clinical studies.

1.14 “Fully Burdened Non-human Interferon Gamma Manufacturing Cost” shall mean the cost of Genentech’s production and testing of Non-human Interferon Gamma, which shall be comprised of the sum of: ***

1.15 “Gene Therapy” shall mean the therapeutic or prophylactic treatment of a human being with: (a) one or more oligonucleotides or nucleotide sequences, in native form

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or chemically modified, which are introduced into the body in free form, bound to a carrier molecule, contained in any molecular vesicle (e.g. a liposome), incorporated into or attached to a vector of any type, contained in any cellular construct and/or contained in any mechanical device or (b) cells which have been manipulated ex vivo using one or more oligonucleotides or nucleotide sequences.

1.16 “Genentech Knowhow” shall mean all proprietary information, methods, processes, techniques and data that are in the possession or control of Genentech on the Effective Date or thereafter during the term of this Agreement, that Genentech is free to license or sublicense, that have not been publicly disclosed, and that are specific and reasonably necessary for the use, sale, offer for sale or importation of Interferon Gamma in the Field of Use in the Territory, but shall not include information regarding the manufacture of Interferon Gamma.

1.17 “Genentech Manufacturing Knowhow” shall mean all proprietary information, methods, processes, techniques and data that are in the possession of Genentech at such time as Genentech determines or is required pursuant to the terms of the Supply Agreement to make a manufacturing technology transfer to Connetics, that are not generally known, and that are specific and reasonably necessary for the manufacture of Interferon Gamma in the Field of Use in the Territory.

1.18 “Genentech Patent Rights” shall mean all patents and patent applications and any patents issuing therefrom, together with any extensions, reissues, reexaminations, substitutions, renewals, divisions, continuations and continuations-in-part thereof (a) that are owned or controlled by Genentech presently or hereafter, during the term of this Agreement, and under which Genentech is free to license or sublicense, and (b) to the extent they claim
or directly relate to Interferon Gamma or its manufacture or use in the Field of Use, including, without limitation, the patent rights granted under that certain license agreement between Genentech and ***, dated July 16, 1990 (the "*** License"), but specifically excluding any rights granted to Genentech under the *** License. Genentech Patent Rights shall include, without limitation, the patents and patent applications listed in Exhibit A attached hereto. Notwithstanding the foregoing, Genentech Patent Rights shall exclude any rights Genentech acquires after the Effective Date of this Agreement under third-party license agreements, with the exception of those acquired under the *** License, unless and until the Parties mutually agree on terms and conditions for the sublicense of such rights from Genentech to Connetics.

1.19 "IND" shall mean Investigational New Drug Application.

1.20 "Interferon Gamma" shall mean a polypeptide having the 126 amino acid sequence set forth on Exhibit B or a variant of such sequence having at least 70% homology thereto, or such polypeptide with one or more additional amino acid residue(s) extending from the N-terminus thereof and/or one or more additional amino acid residue(s) extending from the C-terminus thereof, such polypeptides including, without limitation, Interferon Gamma-1B.

1.21 "Interferon Gamma-1B" shall mean a single chain polypeptide containing the 140 amino acid sequence set forth on Exhibit C hereto, i.e., the active ingredient in the ACTIMMUNE® (Interferon Gamma-1B) Injection product.

1.22 "Licensed Product" shall mean any pharmaceutical formulation containing Interferon Gamma whether alone or together with or incorporated into any other substance or product or material or device, whether active or not, and which (i) but for the licenses *** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.

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granted hereunder, the manufacture, use, sale, offer for sale or importation of which in the Territory would infringe or contribute to the infringement of Genentech Patent Rights in the Territory, or (ii) is based upon or incorporates or utilizes Genentech Knowhow. For purposes of clarification, it is understood that this definition shall not include any pharmaceutical formulation which induces the presence or activity of Interferon Gamma \textit{in vivo}, or the DNA encoding Interferon Gamma for Gene Therapy, or other biological techniques aimed at establishing or modulating endogenous Interferon Gamma \textit{in vivo}.

1.23 “NDA” shall mean New Drug Application.

1.24 “NDC” shall mean National Drug Code.

1.25 “Net Sales” shall mean, as to each calendar quarter, the gross invoiced sales prices charged for all Licensed Products sold by Connetics and its sublicensees in arm’s length transactions to independent third parties during such quarter, after deduction of the following items paid by Connetics and its sublicensees during such calendar quarter with respect to sales of Licensed Products regardless of the calendar quarter in which such sales were made, provided and to the extent that such items are incurred or allowed and do not exceed reasonable and customary amounts in the market in which such sales occurred:

(i) ***

(ii) ***

(iii) ***

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Notwithstanding the foregoing, no deduction shall be made for bad debt expense.

1.26 “Party” shall mean Genentech or Connetics, and, when used in the plural, shall mean both of them.

1.27 “PLA” shall mean Product License Application.

1.28 “Territory” shall mean the United States of America and its territories and possessions.

1.29 “Transfer Date” shall mean, unless otherwise mutually agreed to by the Parties, the last day of the second full calendar month following the first delivery by Connetics to Genentech of Connetics’ labeling and packaging materials for Genentech’s use in labeling and packaging Finished Product, pursuant to a purchase order submitted by Connetics and accepted by Genentech, to be sold commercially by Connetics for treatment of CGD, provided that the activities set forth on Exhibit H have been completed.

2.0 License Grant

2.1 Patent and Knowhow License Grant

(a) Genentech grants to Connetics an exclusive license, even as to Genentech, under Genentech Patent Rights and under Genentech Knowhow to use, sell, offer

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for sale and import (but not to make or have made) Licensed Products in the Field of Use in the Territory, (excluding, with respect to the fields of 
(i) scleroderma and (ii) infectious disease or condition caused by human papillomavirus, Licensed Products containing any form of Interferon Gamma other 
than Genentech Gamma Interferon Δ3, as that term is defined in the *** License). Notwithstanding the foregoing, Genentech reserves the right to use (but not 
to import, offer for sale or sell) Licensed Products within the Field of Use for research purposes.

(b) Genentech grants to Connetics a non-exclusive license under Genentech Patent Rights and under Genentech Knowhow to use, sell, offer for 
sale and import (but not to make or have made) Licensed Products containing any form of Interferon Gamma other than Genentech Gamma Interferon Δ3 (as 
that term is defined in the *** License) in the Territory in the fields of: (i) scleroderma and (ii) infectious disease or condition caused by human 
papillomavirus.

(c) Genentech grants to Connetics a non-exclusive sublicense under the *** License Rights to use, sell, offer for sale and import Licensed 
Products (excluding Licensed Products containing *** Gamma Interferon Δ0 as that term is defined in the *** License) in the Territory in the fields of 
scleroderma and infectious disease or condition caused by human papillomavirus.

(d) Genentech grants to Connetics a non-exclusive license under Genentech Patent Rights to make or have made Licensed Products in the Field 
of Use for use and sale in the Territory.

(e) Genentech grants to Connetics a non-exclusive license under Genentech Patent Rights and Genentech Knowhow to use non-human animal 
species derived

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homologues of Interferon Gamma (Non-human Interferon Gamma) for non-commercial research purposes to support the Field of Use in the Territory.

Except as expressly granted herein, there are no implied licenses under the Genentech Patent Rights or any other intellectual property rights owned or controlled by Genentech.

2.2 Trademark License Grant

(a) Genentech hereby grants to Connetics a non-exclusive, royalty-free license to use the trademark, ACTIMMUNE, for the advertising, promotion, marketing, distribution and sale of Licensed Products in the Territory. Connetics shall have the right to grant sublicenses to such non-exclusive license, subject, however, to the prior written consent of Genentech, which consent shall not be unreasonably withheld. Genentech agrees not to grant any other licenses to use the ACTIMMUNE trademark without the consent of Connetics, which consent shall not be unreasonably withheld.

(b) Use of the Mark. In using the ACTIMMUNE mark, Connetics shall display said mark in upper case letters or otherwise display it in a style or size of print distinguishing the mark from any accompanying wording or text. Where feasible, Connetics shall display the registration symbol ® to the right of and slightly above or below the last letter of the word, ACTIMMUNE. Prior to any new use by Connetics of the ACTIMMUNE mark on product packaging or package inserts for the Licensed Products, Connetics shall notify and provide Genentech with an example of the proposed use for approval by Genentech, which approval shall not be unreasonably withheld or delayed. Such additional use, with respect to the ACTIMMUNE mark, shall automatically become a part of the license grant under Section 2.2(a) above.
(c) Quality Control. If Connetics uses the ACTIMMUNE mark for Licensed Products, such products shall be of at least the quality described in the Specifications therefor as defined in the Supply Agreement.

(d) Ownership. Connetics hereby acknowledges Genentech’s exclusive right, title and interest in and to the ACTIMMUNE mark and agrees that it will not at any time do, or cause to be done, any act or thing contesting or in any way impairing or intending to impair the validity of and/or Genentech’s exclusive right, title and interest in and to the ACTIMMUNE mark. Connetics will not in any manner represent that it owns the ACTIMMUNE mark and hereby acknowledges that its use of the ACTIMMUNE mark as set forth in Section 2.2(b) above shall not create any rights, title or interest in or to the ACTIMMUNE mark in its favor, but that all use of the ACTIMMUNE mark by Connetics shall inure to the benefit of Genentech.

2.3 Sublicenses.

(a) Connetics may grant sublicenses under the rights granted in Section 2.1(d) on thirty (30) days prior written notice to Genentech, subject to Genentech’s prior written approval, which approval shall be at Genentech’s sole discretion. Genentech agrees that *** is acceptable to Genentech as a Connetics’ sublicensee under the rights granted in Section 2.1(d) for the purpose of manufacturing and supplying Bulk Product and/or Finished Product to Connetics, and/or to its sublicensees under Sections 2.1(a), (b) and (c). In the event that Genentech approves the grant of a sublicense under Section 2.1(d), Genentech may in its sole discretion, or as agreed by the Parties in the Supply Agreement, agree to grant to Connetics and such approved sublicensee a non-exclusive license under Genentech Manufacturing Knowhow solely to make or have

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made Licensed Products for use and sale by Connetics and its sublicensees in the Field of Use in the Territory, and Genentech shall thereafter disclose to Connetics and such sublicensee such Genentech Manufacturing Knowhow as soon as reasonably possible.

(b) Connetics may grant one or more sublicenses under the rights granted in Sections 2.1(a), (b), (c) and (e) in any applicable Area of the Field of Use, on thirty (30) days prior written notice to Genentech, subject to Genentech’s prior written approval, which approval shall not be unreasonably withheld.

(c) Notwithstanding the above, Connetics may grant one sublicense to InterMune (as defined in Section 3.1) under any or all of the rights granted in Sections 2.1 and 2.2(a) above without Genentech’s prior written approval. InterMune (but no other sublicensee of Connetics) may grant further sublicenses under Sections 2.1 and 2.2(a) to the extent that Connetics has the right to do so pursuant to the provisions of this Section 2.3 and Section 2.2(a). Connetics and InterMune shall give Genentech a copy of any sublicense agreement entered into by either of them with a third party pursuant to this Agreement as soon as reasonably possible after execution, provided that Connetics and InterMune may each redact from such copies text of information or provisions that are not relevant to this Agreement and the rights and obligations of the Parties hereunder. Genentech agrees to permit InterMune to perform Connetics’ rights and obligations under Section 2.2(b), (c) and (d), Section 2.5, Sections 3.1 through 3.8 and Article 4.0 of this Agreement (excluding matters related to any alleged breach of the Agreement, or dispute between the Parties concerning the performance of this Agreement, under such enumerated Sections and Article), to the extent such rights and obligations are sublicensed to InterMune by Connetics, and Genentech agrees to deal with InterMune in lieu of Connetics as if it were Connetics.
hereunder for purposes of performance under such enumerated Sections and Article, provided that Connetics shall remain liable and responsible for performance of all of the obligations of Connetics and InterMune under this Agreement. In the event that Connetics sublicenses all of its rights under Section 2.1 and 2.2(a) to InterMune pursuant to a written sublicense which provides that InterMune (and not Connetics) shall make, have made, use, sell, offer for sale, import and develop Licensed Products in all Areas of the Field of Use in the Territory, then Genentech agrees to permit InterMune to also perform Connetics’ rights and obligations under Articles 5.0 and 6.0 and Sections 8.2 through 8.8 of this Agreement (excluding matters related to any alleged breach of the Agreement, or dispute between the Parties concerning the performance of this Agreement, under such enumerated Sections and Articles), and Genentech also agrees to deal with InterMune in lieu of Connetics as if it were Connetics hereunder for purposes of performance under such enumerated Sections and Articles, provided that Connetics shall remain liable and responsible for performance of all of the obligations of Connetics and InterMune under this Agreement. In the event that InterMune sublicenses any of its rights to a third party pursuant to this Agreement, such sublicensee shall not have the right to perform the rights and obligations of Connetics or InterMune under the Sections and Articles enumerated above, and Genentech shall not have any obligation to deal directly with such sublicensee. Notwithstanding the above provisions of this Section 2.3(c), with respect to any dispute concerning InterMune’s performance, or alleged breach by InterMune, of any applicable term of this Agreement, Genentech shall have the right to deal directly with Connetics, and to proceed either against InterMune or directly against Connetics, in Genentech’s sole discretion, to enforce this Agreement.
In the event of the grant of any sublicense by Connetics (including such grant to InterMune) or by InterMune, the sublicensee shall be subject to all of the applicable obligations of Connetics hereunder. Connetics guarantees to Genentech the performance of Connetics’ applicable obligations hereunder by Connetics’ sublicensees and by InterMune’s sublicensees.

2.4 Grant Back License. Connetics hereby grants to Genentech under any Connetics Patent Rights and Connetics Knowhow, a nonexclusive, sublicenseable license in the Territory to make, have made, use, sell, offer for sale and import Interferon Gamma for any use outside of the Field of Use, with a royalty rate of *** payable to Connetics on net sales of Interferon Gamma by Genentech, its affiliates and its sublicensees covered by such Connetics Patent Rights or incorporating such Connetics Knowhow. Genentech shall have the right to grant sublicenses under such license, subject to the prior written approval of Connetics, which approval shall not be unreasonably withheld. The license granted to Genentech under this Section 2.4 shall expire on the later of: (a) the expiration of the last to expire of any Connetics Patent Rights or (b) if Connetics Knowhow was used, twenty (20) years from the first commercial sale of Interferon Gamma outside the Field of Use by Genentech, its affiliates or its sublicensees hereunder. As used herein, “net sales” shall have the equivalent definition given to Net Sales in Section 1.25 above.

2.5 Data Transfer and Cooperation

(a) Genentech shall provide Connetics with reasonable access to all such relevant information and materials in its possession (subject to Genentech’s own internal reasonable needs for the information and materials) that Connetics reasonably needs to develop and commercialize Licensed Products in the Field of Use under the license granted

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to Connetics under Section 2.1 above. Connetics shall submit requests for such information to Genentech’s Clinical Collaborations Operations Department - Medical Affairs at the address set forth at the beginning of this Agreement. Access to such information and materials shall be made in a timely and orderly fashion and in a manner such that the value of the accessed information is preserved in all material respects.

(b) Connetics shall provide Genentech with reasonable access to such relevant information and materials in its possession as is reasonably necessary for Genentech to exercise the license rights granted by Connetics under Section 2.4 and Genentech shall submit requests for such information to Connetics’ Vice President—Intellectual Property at the address set forth at the beginning of this Agreement. Access to such information and materials shall be made in a timely and orderly fashion and in a manner such that the value of the accessed information is preserved in all material respects.

(c) Commencing on May 1, 1998 Connetics or its sublicensees shall be responsible for any costs associated with maintaining the Genentech breeding colony of interferon gamma gene knock-out mice at Charles River Labs (the “Knock-Out Mice”). In consideration for Connetics paying these costs, Genentech hereby transfers all ownership of such particular Knock-Out Mice to Connetics, subject to Genentech’s right to use such Knock-Out Mice and the progeny thereof for Genentech’s own research purposes to the extent such Knock-Out Mice are not being used (or planned to be used) by Connetics or its sublicensees. If Connetics and its sublicensees wish to discontinue the maintenance of such Knock-Out Mice colony, Connetics shall give Genentech sixty (60) days prior notice and the right to take over such maintenance, at Genentech’s sole discretion, before Connetics discontinues such maintenance. Connetics acknowledges that Genentech has, prior to the
Effective Date hereof, transferred interferon gamma gene knock-out mice to other third parties.

(d) Connetics shall use its Best Efforts to obtain a license from the FDA, which shall include obtaining a U.S. license number and an NDC number, to enable the effective transfer from Genentech to Connetics of the PLA for CGD on file with the FDA (the “CGD PLA”). Genentech shall use its Best Efforts to assist such transfer, to the extent reasonably requested by Connetics. Genentech also shall, before the Transfer Date, reasonably assist Connetics in initiating Connetics’ sales of Licensed Product in the Area of the Field of Use of CGD by transferring to Connetics information reasonably requested by Connetics that relates to such sales efforts for CGD. Connetics shall reimburse Genentech for all reasonable costs associated with Genentech’s providing of such information within ninety (90) days of Connetics’ receipt of an invoice of such cost from Genentech.

(e) Genentech shall transfer the CGD PLA, IND and copies of all material correspondence with the FDA regarding such PLA and IND to Connetics as soon as reasonably possible after the Effective Date of this Agreement and Connetics shall be responsible for all activities, at its own cost, necessary to maintain the CGD PLA and IND and keep them active with the FDA after such date. Connetics shall reimburse Genentech for 50% of all reasonable costs associated with Genentech’s transfer of the CGD PLA, IND and such FDA correspondence within ninety (90) days of Connetics’ receipt of an invoice of such cost from Genentech.

(f) Connetics shall not commence marketing and sales of Finished Product prior to the Transfer Date. On the Transfer Date, Genentech shall transfer to Connetics the responsibility for all marketing and sales of Finished Product in the Field of Use in the
Territory, provided that all the activities listed on Exhibit H attached hereto are completed. The Parties shall use Best Efforts to complete the tasks set forth on Exhibit H as expeditiously as possible.

(g) Genentech shall provide Connetics with reasonable access to relevant data and regulatory information in its possession in the form existing as of the Effective Date, whether written or electronic, including all clinical safety data and clinical efficacy data that are related to the manufacture, use and sale of Interferon Gamma within the Field of Use and the right to cross-reference Genentech’s IND, ELA, and PLA information for Interferon Gamma in any Genentech regulatory filings related to Interferon Gamma within the Field of Use. Other than as expressly set forth herein, Genentech shall have no further obligation with respect to Connetics’ efforts to obtain the FDA license referred to in Section 2.5(d) above. At Genentech’s sole discretion, Genentech may participate in regulatory filings in the Field of Use in the Territory if the Parties agree that Genentech’s participation in such regulatory filings would expedite the approval and commercialization of a Licensed Product. Connetics shall reimburse Genentech for all reasonable costs associated with Genentech’s providing of data and regulatory information and referencing within ninety (90) days of Connetics’ receipt of an invoice of such cost from Genentech. Connetics shall submit requests for such information to Genentech’s Clinical Collaborations Operations Dept. - Medical Affairs at the address set forth in the beginning of this Agreement. Such requests shall not be submitted more than two (2) times in any twelve (12) month period, unless such requests concern information that is critical to product registration activities. Access to such information shall be made in a timely and orderly fashion and in a manner such that the value of the accessed information is preserved in all material respects.
(h) To the extent reasonably requested by Genentech, Connetics shall provide Genentech with access to all data and regulatory information in its possession, whether written or electronic, in the form existing as of the date of Genentech’s request, including all clinical safety data and clinical efficacy data, that directly relates to the use of Interferon Gamma outside the Field of Use and shall give Genentech the right to cross-reference Connetics’ IND, ELA, BLA and PLA information, if applicable, in any Genentech regulatory filings that are related to the use or sale of Interferon Gamma outside the Field of Use. Genentech shall reimburse Connetics for all reasonable actual costs associated with Connetics’ providing of data and regulatory information and referencing within ninety (90) days of the receipt of an invoice of such cost by Genentech from Connetics. Such requests shall not be submitted more than two (2) times in any twelve (12) month period, unless such requests concern information that is critical to product registration activities. Access to such information shall be made in a timely and orderly fashion and in a manner such that the value of the accessed information is preserved in all material respects.

(i) Commencing from Genentech’s first delivery to Connetics or Intermune of Finished Product for clinical studies in accordance with the Supply Agreement, Connetics shall thereafter be responsible for supplying ACTIMUNE free of charge to, and funding (if any) of, the third party sponsors of the clinical studies listed in Exhibit D attached hereto and incorporated herein. Connetics shall enter into clinical research agreements with such third party sponsors governing such studies that commence after the Effective Date hereof. With respect to clinical research agreements between Genentech and such sponsors in effect prior to the Effective Date, Connetics shall replace Genentech, pursuant to an
j) As of the Transfer Date, Connetics shall conduct an indigent patient program for Licensed Products sold for use in the field of CGD. As soon as reasonably possible after Genentech transfers information regarding patients who have participated in Genentech’s indigent patient program, Connetics will inform Genentech whether or not such patients will be eligible and participating in Connetics’ indigent patient program.

3.0 Product Development and Milestones

3.1 Commercialization Milestones.

   (a) Connetics shall use its Best Efforts to develop, seek FDA clearance for marketing of, commercialize and sell Licensed Products in the Territory in all Areas of the Field of Use. The Parties acknowledge that a new company, named InterMune Pharmaceuticals, Inc. (“InterMune”), has been incorporated to conduct development and commercialization of Licensed Products in the Field of Use pursuant to an appropriate sublicense from Connetics to InterMune. Connetics agrees to perform the following Commercialization Milestones no later than the date set forth below opposite the appropriate Commercialization Milestone description:

<table>
<thead>
<tr>
<th>Commercialization Milestone</th>
<th>Date of Completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Completion of the formation of InterMune</td>
<td>May 1, 1998</td>
</tr>
<tr>
<td>(b) Execution of a sublicense agreement granting to InterMune</td>
<td>June 1, 1998</td>
</tr>
<tr>
<td>rights, as permitted in this Agreement,</td>
<td></td>
</tr>
</tbody>
</table>
necessary to perform development of Licensed Products in the Field

<table>
<thead>
<tr>
<th>Milestone Description</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>(c) Closing of at least *** in equity financing of InterMune by third parties and/or</td>
<td>July 15, 1998</td>
</tr>
<tr>
<td>Connetics</td>
<td></td>
</tr>
<tr>
<td>(d) Closing of at least another additional *** in equity financing of InterMune by</td>
<td>September 1,</td>
</tr>
<tr>
<td>(e) Enrollment and active participation of the first patient in the first new clinical trial for a Licensed Product in the Field of Use in the Territory</td>
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<td>October 1, 1998</td>
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(b) If Connetics fails to perform any of the Commercialization Milestones described in 3.1 (a) through (e) inclusive by the applicable Date of Completion for any reason within Connetics’ control, then, notwithstanding the termination provisions in Section 11.2 below, Genentech shall have the right to terminate this Agreement and the licenses granted to Connetics hereunder, upon written notice to Connetics, which termination shall become effective thirty (30) days after Genentech’s sending written notice of such termination, unless such Commercialization Milestone has been completed prior to the expiration of such thirty day period. If Connetics fails to perform any of the Commercialization Milestones for causes beyond Connetics’ control, Genentech shall not have the termination rights above, provided that Connetics has mitigated such causes to the extent it can reasonably do so. If Connetics fails to reasonably mitigate such causes, Genentech will have the termination rights described above. In addition, if Genentech

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exercises such termination rights above, Genentech shall be automatically granted a co-exclusive (with Connetics and Connetics’ sublicensees), sublicenseable, royalty-free, worldwide license: (i) to the result of efforts made by Connetics and its sublicensees in the development of Licensed Products hereunder, (ii) to use all regulatory submissions made by Connetics and its sublicensees hereunder, and (iii) under all Connetics Patent Rights and Connetics Knowhow, arising from the efforts made by Connetics and its sublicensees hereunder in the research and development of Licensed Products, to make, have made, use, sell, offer for sale or import Licensed Products. Upon Genentech’s exercise of such termination right described above, Connetics shall promptly provide Genentech with copies of all related documentation, whether written or electronic, and materials, including biological materials, in the form existing as of the effective date of such termination, reasonably necessary for Genentech to exercise its license rights under this Section 3.1(b). Such transfer shall be made in an orderly fashion and in a manner such that the value in what is being transferred is preserved in all material respects. The foregoing shall constitute Genentech’s exclusive remedies for Connetics failure to complete one or more of the Commercialization Milestones above, provided, however, that Genentech’s rights and remedies for breach of other provisions of this Agreement, and under the Supply Agreement and the Stock Agreement, shall remain in full force and effect.

3.2 Diligence

(a) Attached hereto as Exhibit E are Connetics’ Clinical Development Milestones (the “Clinical Development Milestones”) for Licensed Products in the Field of Use and the Dates of Completion for each such milestone. Connetics shall use its Best
Efforts to adhere to the Dates of Completion as set forth in Exhibit E. Connetics shall notify Genentech in writing when it achieves a Clinical Development Milestone.

(b) From time to time, Connetics may suggest modifications to the Clinical Development Milestones based on new information. Such modifications shall be effective only as mutually agreed upon, in writing, by the Parties. Genentech shall consider such requested modifications in good faith and shall agree to any modifications that are reasonably necessary to achieve the overall objectives of the development of Licensed Product hereunder.

(c) In the event that Connetics determines that it will be unable to meet any Date of Completion for a Clinical Development Milestone due to an event within Genentech’s control, including without limitation, delay in the performance by Genentech of any of its obligations hereunder (e.g. the transfer of technology or materials, including the supply of Interferon Gamma-1B), Connetics shall give prompt notice to Genentech of such inability and shall specify the amount of delay Connetics believes resulted from such event within Genentech’s control. Unless Genentech disagrees in writing on reasonable grounds with the amount of such delay specified by Connetics, such Date of Completion will automatically be extended by the length of time of the delay. In the event Genentech disagrees in writing on reasonable grounds with the amount of delay specified by Connetics, the Parties shall negotiate a new Date of Completion in good faith.

(d) In the event that Connetics determines that it will be unable to meet any Date of Completion for a Clinical Development Milestone due to an event which would be considered a force majeure (as described in Section 12.9), Connetics shall give prompt written notice to Genentech of such inability and the length of the delay Connetics believes...
resulted from such force majeure. Unless Genentech disagrees in writing on reasonable grounds with the length of such delay specified by Connetics, such Date of Completion will be automatically extended by such specified length of time of the delay. In the event Genentech disagrees in writing on reasonable grounds with the length of delay specified by Connetics, the Parties shall negotiate a new Date of Completion in good faith.

(e) In the event that Connetics determines that it will be unable to meet any Date of Completion for a Clinical Development Milestone for reasons other than (i) force majeure and/or (ii) an event within Genentech’s control, Connetics shall notify Genentech of such inability, identifying the nature of the inability with reasonable specificity and may ask Genentech for a reasonable extension of time in which to complete such Clinical Development Milestone. In Genentech’s sole discretion, Genentech may grant Connetics such an extension to complete such Clinical Development Milestone.

(f) Except as set forth in Sections 3.2(c) or 3.2(d) or in the event that Genentech shall have agreed to an extension of the time to complete a Clinical Development Milestone as set forth in Section 3.2(e), if Connetics fails to complete a Clinical Development Milestone by the corresponding Date of Completion with respect to one or more of the Areas of the Field of Use (other than in the dermatological Area of the Field of Use as described in Section 1.12(a) above) Genentech shall have the right to terminate this Agreement with respect to such Area(s) of the Field of Use, by providing Connetics written notice thereof, and the termination of the Agreement with respect to such Area(s) of the Field of Use shall be effective thirty (30) days after Connetics’ receipt of such notice unless such Clinical Development Milestone shall have been met prior to the expiration of such thirty (30) day period, and such termination shall be Genentech’s exclusive remedy for such failure.
of Connetics to complete such Clinical Development Milestone. Upon such termination of the Agreement with respect to such Area(s) of the Field of Use: (i) Genentech shall automatically have all the rights set forth in Sections 11.3(a) and (b) solely with respect to such Area(s) of the Field of Use; and (ii) any sublicense(s) granted by Connetics with respect to such Area(s) of the Field of Use shall not automatically terminate, but instead, Genentech shall have the option to either terminate or continue this Agreement with respect to such Area(s) of the Field of Use with such sublicensee(s).

3.3 Review of Clinical Development Plan and Marketing Programs. On or about each August 1 during the term of this Agreement, Connetics shall supply Genentech with a report on Connetics’ development and marketing programs for Licensed Products in the Field of Use in the Territory. The report shall include the following: (i) a description of Connetics’ progress in such programs during the twelve (12) months prior to the date of each such report, (ii) a description of Connetics’ planned development and marketing programs for the twelve (12) months after the date of each such report, (iii) a copy of the most recent version of the Clinical Development Milestones (if not previously provided to Genentech), (iv) a copy of all previous versions of the Clinical Development Milestones (if not previously provided to Genentech), (v) an explanation of any discrepancies between Connetics’ progress during the prior twelve (12) months and the Clinical Development Milestones and (vi) a proposal to address such discrepancies, as contemplated under Section 3.2. Genentech shall have the right to comment on the Clinical Development Milestones and the development and marketing programs, and at Genentech’s discretion, the Parties shall meet to discuss and agree upon changes to the Clinical Development Milestones.
3.4 New Delivery Forms. Connetics shall have the right to develop and obtain regulatory approval for the marketing of new delivery forms of Interferon Gamma for use in Licensed Products in the Field of Use in the Territory.

3.5 Costs of Development. Connetics shall be responsible for all aspects and costs of development, regulatory approval and registration of Licensed Products.

3.6 Joint Development and Marketing Activities. Upon written notice to Genentech, Connetics and InterMune shall be permitted to discuss and enter into agreements and participate in joint development and marketing activities for Licensed Products in the Field of Use outside the Territory with other Genentech Interferon Gamma licensees.

3.7 Compliance with Law and Safety and Adverse Event Reporting.

(a) Connetics shall conduct clinical trials hereunder, and shall make, use, sell and distribute Licensed Products in accordance with all applicable laws and regulations. Genentech and Connetics shall make available to each other during the term of this Agreement all safety data obtained which relates to the use of Licensed Products in the Field of Use. Connetics will provide to Genentech’s Medical Information and Drug Experience department at the time of filing a copy of each adverse event report or any report, including summary reports, it is required to file under Title 21 or any other applicable provision of the C.F.R. regarding Interferon Gamma. Genentech will provide Connetics at the time of filing with a copy of each adverse event report or any report, including summary reports, it is required to file regarding Interferon Gamma under Title 21 or any other applicable provision of the C.F.R.

(b) Connetics shall maintain a safety database for all Licensed Products and clinical trials conducted hereunder and shall submit to regulatory agencies all adverse
event and safety reports required to be filed pursuant to Title 21 or any other applicable provision of the C.F.R. Connetics shall also be responsible for providing product, medical and clinical information regarding Licensed Product to its customers.

3.8 Clinical Development Reports. During the course of clinical development of Licensed Products and clinical studies conducted by Connetics hereunder, Connetics shall submit to Genentech the reports listed on Exhibit F attached hereto and incorporated herein. Connetics shall submit such reports to Genentech as promptly as reasonably practicable after such reports are completed or such applicable information is available.

3.9 Technology Outside the Field of Use

(a) Upon mutual written amendment to this Agreement, the Parties may expand the Field of Use, subject to the terms and conditions for supply of Interferon Gamma 1-B set forth in the Supply Agreement, the payments set forth in Sections 8.2 through 8.8 below inclusive and all other applicable obligations of Connetics under this Agreement.

(b) Connetics may request an expansion of the Field of Use in the Territory, by providing Genentech with a written letter of intent which incorporates the terms and conditions specified in the Supply Agreement and Sections 8.2 through 8.8 of this Agreement and sets forth a detailed clinical development plan and reasonable proposed timeline (through FDA clearance) for developing the additional medical indication(s) sought. Such letter of intent shall be deemed Confidential Information of Connetics. Upon receipt of such letter of intent, unless Genentech is conducting research in, or developing, Interferon Gamma for such specified use, is already engaged in negotiations with a third party for such specified use, or is prevented by prior written agreements to grant rights to such additional indications to Connetics, Genentech shall negotiate exclusively in good faith with Connetics,
for a period of sixty (60) days on a one time basis only for each such new indication outside the Field of Use, to expand the Field of Use as proposed in the letter of intent on terms substantially similar to those contained in this Agreement. If the Parties do not reach mutual written agreement with respect to such proposed expansion of the Field of Use within sixty (60) days, Genentech shall continue to have the right to license its rights to such proposed additional indications for Interferon Gamma outside the Field of Use to third parties other than Connetics, provided that, for a period of six (6) months after the 60 day exclusive negotiation period with Connetics, the milestone fee and royalty terms offered by Genentech to third parties for such indications are not more favorable to such third parties than those in the final offer made by Connetics.

(c) Prior to offering any third party an opportunity to obtain any right or license under Genentech Patent Rights, Genentech Knowhow, or License Rights to use, sell, offer for sale or import Licensed Products for any indication outside the Field of Use in the Territory, Genentech shall first offer to Connetics to expand the Field of Use to include such indication, in accordance with Section 3.8(d) below. Such obligation to first offer to Connetics such indication outside the Field of Use shall apply only to the first time Genentech wishes to offer rights to another party to such indication outside the Field of Use.

(d) Genentech may offer to expand the Field of Use by written notice to Connetics (“Offer Notice”). Upon receipt of such Offer Notice, Connetics shall have thirty (30) days to provide Genentech with a written letter of intent which incorporates the terms and conditions specified in the Supply Agreement and Sections 8.2 through 8.8 of this Agreement. Upon receipt of such letter of intent, Genentech shall negotiate exclusively in good faith with Connetics, for a period of thirty (30) days on a one time basis only for each indication outside the Field of Use.

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such new indication outside the Field of Use, to expand the Field of Use as proposed in the letter of intent on terms substantially similar to those contained in this Agreement. If the Parties do not reach mutual written agreement with respect to such proposed expansion of the Field of Use within 30 days, Genentech shall continue to have the right to license its rights to such proposed additional indications for Interferon Gamma outside the Field of Use to third parties other than Connetics. To remain under consideration as a potential licensee for such rights to Interferon Gamma outside the Field of Use, within ninety (90) days of receipt of Genentech’s Offer Notice, Connetics shall provide Genentech with a detailed written clinical development plan and reasonable proposed timeline for developing (through FDA clearance) the additional medical indication(s) sought, which development plan shall be deemed the Confidential Information of Connetics.

4.0 Supply of Interferon Gamma-1B

4.1 Bulk Product and Finished Product. Genentech shall supply Connetics with, and Connetics shall purchase, Bulk Product for clinical studies and for sales of Licensed Product and Finished Product for commercial sale of Licensed Product to treat CGD and osteopetrosis and for clinical studies, pursuant to the terms and conditions of the Supply Agreement.

4.2 Supply of Non-human Interferon Gamma. Upon Connetics’ reasonable request and in Genentech’s sole discretion, Genentech may choose to sell to Connetics Non-human Interferon Gamma at a price equal to ***

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Gamma to Connetics or (b) produce additional amounts of Non-human Gamma Interferon in the event its current inventory is depleted.

5.0 Intellectual Property Rights

5.1 Ownership. Genentech shall retain title to Genentech Patent Rights, Genentech Knowhow, Genentech Manufacturing Knowhow, the ACTIMMUNE mark, and to any patent rights and knowhow related to Interferon Gamma or Licensed Products developed solely by Genentech. Connetics shall retain title to Connetics Patent Rights and Connetics Knowhow and to any patent rights and knowhow related to Interferon Gamma and Licensed Products developed solely by Connetics. Except as expressly provided herein, each Party shall own and shall have the exclusive right to exploit all intellectual property rights owned or acquired by such Party.

5.2 Patent Prosecution and License Fees

(a) With the exception of Genentech Patent Rights under the *** License, Genentech shall be responsible for the prosecution and maintenance of the Genentech Patent Rights in the Territory at Genentech’s expense, in consultation with Connetics. Genentech shall be responsible for the prosecution and maintenance and outside counsel fees associated therewith of the Genentech Patent Rights under the *** License in the Field of Use in the Territory at Connetics’ expense, upon prior consultation with and approval from Connetics, which approval shall not be unreasonably withheld or delayed. Genentech shall keep Connetics promptly informed of the status of prosecution of Genentech Patent Rights in the Territory, including providing copies of all material correspondence with the U.S. Patent and Trademark Office. Connetics shall have the right to comment upon such

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prosecution and Genentech agrees to take such comments into consideration reasonably in advance of any action taken by Genentech in such prosecution.

(b) Connetics shall assist Genentech in prosecuting and maintaining the Genentech Patent Rights as contemplated by Section 5.2(a) above.

c) At least thirty (30) days prior to the time each benchmark payment of *** under the *** License becomes due during the term of this Agreement, Genentech shall notify Connetics of such payment due and Connetics shall have the option of paying such benchmark payment, on Genentech’s behalf, when due to ***. In the event that Connetics chooses not to pay the benchmark payment when due, Connetics shall so notify Genentech and Genentech shall have the option of paying such benchmark payment. If Genentech pays such benchmark payment, Connetics shall reimburse Genentech for such payment within thirty (30) days of receipt of Genentech’s request for reimbursement.

5.3 Patent Infringement

(a) If either Party learns that a third party is infringing Genentech Patent Rights or Connetics Patent Rights, it shall promptly notify the other in writing. The Parties shall use reasonable efforts in cooperation with each other to stop such patent infringement without litigation.

(b) Genentech and Connetics each shall have the first opportunity to take the appropriate steps to remove the infringement of its own Patent Rights which claim Interferon Gamma and/or its manufacture or use in the Field of Use including, without limitation, initiating suit. In either case, if such Party decides not to take such steps with respect to its own Patent Rights within one hundred twenty (120) days of discovering or being notified of the infringement, the other Party may do so. Each of the Parties agrees to

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provide reasonable assistance to the other in taking such steps. Any legal action taken under this section will be at the expense of the Party by whom suit is filed and will be controlled by the Party bringing suit. The Party not bringing suit may choose to be represented in any such action by counsel of its own choice at its own expense. The Party bringing suit shall be reimbursed for its costs associated with bringing suit with the proceeds of any damages or costs recovered. Any monies remaining shall be split between the Parties on an equitable basis proportional to their respective damage from the infringement. If both Parties bring suit, equitable apportionment of the costs and damages to be recovered shall be agreed upon before the filing of the suit.

5.4 Third Party Rights. If a notice of infringement is received by, or a suit is initiated against, either of Connetics or Genentech with respect to Licensed Products or the ACTIMMUNE mark, the Parties will in good faith discuss the best way to respond.

5.5 Trademark Infringement

(a) If either Party learns that a third party is infringing the ACTIMMUNE mark, it shall promptly notify the other in writing. The Parties shall use reasonable efforts in cooperation with each other to stop such trademark infringement without litigation.

(b) Genentech shall have the first opportunity to take the appropriate steps to remove the infringement of the ACTIMMUNE mark, including, without limitation, initiating suit. If Genentech decides not to take such steps within one hundred twenty (120) days of discovering or being notified of the infringement, Connetics may do so. Each of the Parties agrees to provide reasonable assistance to the other in taking such steps. Any legal action taken under this section will be at the expense of the Party by whom suit is filed and will be controlled by the Party bringing suit. The Party not bringing suit may choose to be
represented in any such action by counsel of its own choice at its own expense. The Party bringing suit shall be reimbursed for its costs associated with bringing suit with the proceeds of any damages or costs recovered. Any monies remaining shall be split between the Parties on an equitable basis proportional to their respective damage from the infringement. If both Parties bring suit, equitable apportionment of the costs and damages to be recovered shall be agreed upon before the filing of the suit.

5.6*** License. If Genentech receives notice that it has acquired any Genentech Patent Rights under the *** License after the Effective Date of this Agreement, Genentech shall notify Connetics in writing of such additional rights as soon as reasonable after Genentech receives such notice.

6.0 Product Promotion

6.1 Promotion. Genentech agrees, and shall require its sublicensees, if any, to agree, not to promote Interferon Gamma or a Licensed Product in the Field of Use in the Territory. Connetics agrees, and shall require its sublicensees to agree, not to promote Interferon Gamma or a Licensed Product outside the Field of Use or outside the Territory.

6.2 Encroachment. In the event that either Party becomes aware of spillover sales of Interferon Gamma by Genentech that is used within the Field of Use or of Licensed Product by Connetics that is used outside the Field of Use, the Parties shall meet and agree in good faith on reasonably appropriate steps (a) to abate such encroachment and (b) to compensate the Party which has suffered encroachment in its field of use by such spillover sales.

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7.0 Confidentiality

In the course of performance of this Agreement, one Party may disclose to the other or receive information from the other relating to the subject matter of this Agreement which information shall be considered to be the disclosing Party’s confidential information, if in the case of a written disclosure, it is designated as confidential at the time of disclosure, or if in the case of oral disclosure, the specific nature of the oral disclosure and its confidentiality is confirmed in writing to the other Party within thirty (30) days of the oral disclosure (the “Confidential Information”). Each Party shall protect and keep confidential and shall not use, publish or otherwise disclose to any third party, except as permitted by this Agreement or with the other Party’s written consent, the other Party’s Confidential Information for a period of five (5) years from the date of termination of this Agreement if it is terminated at any time within five (5) years after the Effective Date of this Agreement, otherwise for a period of three (3) years from date of termination or expiration of this Agreement. A Party may disclose the other Party’s Confidential Information to its sublicensees hereunder, provided that such sublicensees are subject to obligations of confidentiality at least equivalent to those set forth in this Article 7. The Parties shall consult prior to the submission of any manuscript for publication to determine if the publication will contain any Confidential Information of the other Party. Such consultation shall include providing a copy of the proposed manuscript to the other Party at least forty-five (45) days prior to the proposed date of submission to a publisher, incorporating appropriate changes proposed by the other Party into the manuscript submission and deleting all of the other Party’s Confidential Information which such Party does not agree to the publication thereof. The foregoing notwithstanding, Confidential Information may be disclosed: (a) during any
official proceeding before a court or governmental agency if reasonably related to that proceeding; (b) as a part of a patent application filed on inventions made under this Agreement, provided that the Party whose Confidential Information is included in such application shall have the opportunity to review such disclosure at least fifteen (15) business days prior to the date of such filing and such Party does not object to such disclosure; and (c) as may be reasonably required to comply with applicable governmental laws or regulations. For the purposes of this Agreement, Confidential Information shall not include such information that:

(i) was known to the receiving Party at the time of disclosure;
(ii) was generally available to the public or was otherwise part of the public domain at the time of disclosure or became generally available to the public or otherwise part of the public domain after disclosure other than through any act or omission of the receiving Party in breach of this Agreement;
(iii) became known to the receiving Party after disclosure from a source that had a lawful right to disclose such information to others; or
(iv) was independently developed by the receiving Party without the use of Confidential Information of the other Party, as evidenced by written records.

If Connetics sublicenses any of its rights hereunder to InterMune pursuant to this Agreement, Genentech and InterMune shall enter into a mutual confidentiality agreement, substantially in the form of this Article 7.0, to protect confidential information that may be disclosed by InterMune to Genentech.
8.0 Up-front Payment, Milestone Payments and Royalties

In consideration for the licenses granted to Connetics by Genentech pursuant to Section 2.0 above, Connetics shall make the following payments to Genentech:

8.1 Up-front Payment. Connetics shall issue to Genentech upon the Original Closing Date (as defined in the Stock Agreement) shares of Connetics Common Stock ("Original Issuance Shares" as defined in the Stock Agreement) with a fair market value equal to two million dollars ($2,000,000), on the terms and conditions set forth in the Stock Agreement. If, on the Second Closing Date (as defined in the Stock Agreement), the aggregate market value of the Original Issuance Shares (based on the Second Issuance Price (as defined in the Stock Agreement)) is less than four million dollars ($4,000,000), Connetics shall issue to Genentech upon the Second Closing Date the number of additional shares of Connetics Common Stock (the "Second Issuance Shares," as defined in the Stock Agreement) equal to the lesser of: (i) the number of shares necessary to increase the aggregate market value of the Original Issuance Shares (based on the Second Issuance Price) to four million dollars ($4,000,000) or (ii) the number of shares necessary to increase the aggregate number of the Company’s shares of Common Stock held by Genentech (exclusive of any shares that Genentech has purchased from parties other than the Company) to 9.9% of the Company’s total outstanding shares of Common Stock as of the close of business on the third trading day before the Second Closing Date, on the terms and conditions set forth in the Stock Agreement. In lieu of all or any portion of the Second Issuance Shares that the Company is obligated to issue to Genentech on the Second Closing Date, the Company may elect to pay
Genentech the cash value of such Second Issuance Shares (based on the Second Issuance Price). The Original Closing and the Second Closing of the stock issuances shall take place as described in the Stock Agreement. In the event that Connetics does not issue to Genentech all of the Second Issuance Shares or the cash value of the Second Issuance Shares, Genentech may, in addition to other remedies available to it by law or in equity, immediately terminate this Agreement and the licenses granted to Connetics hereunder. Such termination by Genentech of the Agreement and the licenses hereunder does not discharge Connetics’ obligation to issue all of the Second Issuance Shares or to pay to Genentech the cash value of the Second Issuance Shares. The up-front payment shall not be creditable against any royalty payments owed by Connetics under Sections 8.3 and 8.4 below.

8.2 Milestone Payments for Licensed Products. Connetics shall make the following cash milestone payments to Genentech:

(a) within thirty (30) days following the dates on which each of the first three (3) NDA’s or BLA’s for a Licensed Product is filed with the FDA by Connetics for a new indication in the Field of Use; provided however, that such milestone payments shall not be paid upon the filing of a NDA or BLA for an osteopetrosis or atypical mycobacterial infection indication.

(b) within thirty (30) days following the date Connetics receives FDA clearance of each new indication for a Licensed Product for commercial sale in the United States; provided however, that such milestone payment shall not be paid upon receipt of FDA clearance for an osteopetrosis or atypical mycobacterial infection indication.

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within thirty (30) days following the first date Connetics’ aggregate Net Sales of all Licensed Products in the Territory in any calendar year.

Notwithstanding the foregoing, upon the expiration or revocation of the last remaining issued patent within the Genentech Patent Rights during the term of this Agreement, each of the milestones payments set forth in (a)-(d) above thereafter shall be reduced by fifty percent (50%). Milestone payments shall not be creditable against any royalty payments owed under Sections 8.3 and 8.4 below.

8.3 Royalties. Connetics shall pay Genentech the following royalties on Net Sales of Licensed Products by Connetics and its sublicensees:

(a) For annual aggregate Net Sales of all Licensed Products in the Territory of up to three million seven hundred thousand dollars ($3,700,000), a royalty rate equal to *** of such Net Sales.

(b) In addition to the payment of the royalty rate specified in (a) above, for annual aggregate Net Sales of all Licensed Products in the Territory exceeding three million seven hundred thousand dollars ($3,700,000), a royalty rate equal to *** of such Net Sales exceeding $3,700,000.

(c) The above royalties shall be payable until the later of: (i) the expiration or revocation of the last remaining issued patent within the Genentech Patent Rights or (ii) twenty (20) years from the Effective Date of this Agreement. Notwithstanding the

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foregoing, upon the expiration of the last to expire issued patent within the Genentech Patent Rights during the term of this Agreement, thereafter each of the
royalty rates set forth in (a) and (b) above shall be reduced by fifty percent (50%).

8.4 Third-Party Royalties. If Genentech or Connetics is required to pay any third party a royalty due to the manufacture, use, sale, offer for sale or
importation of a Licensed Product in the Territory for or by Connetics or its sublicensees, Connetics shall be responsible for the payment of *** of such
third-party royalty, provided however, that Connetics may deduct from the royalties payable to Genentech under Section 8.3 above *** of such
third party royalties incurred only due to use patents in the Field of Use in the Territory, up to a maximum total deduction of *** percentage points from the
royalties payable by Connetics to Genentech under Section 8.3. For purposes of clarification, such deductions shall not apply to any benchmark payment
under the *** License made by Connetics pursuant to Section 5.2(c) above. Attached hereto as Exhibit G is a list of all such royalty obligations to third
parties known to Genentech as of the Effective Date without diligent search. No later than thirty (30) days from the Effective Date, Genentech shall complete
a reasonable internal investigation of its records and update Exhibit G, as necessary, to accurately reflect all such royalty obligations to third parties to the
best of Genentech’s knowledge; provided however, Connetics acknowledges that Genentech has no obligation to conduct due diligence or any investigation
with respect to third party patent rights related to Licensed Products. Genentech shall notify Connetics in writing during the term of this Agreement if it
becomes aware of any additional Genentech third party royalty obligations.

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8.5 Royalty Payments. Royalty payments shall be made to Genentech quarterly within ninety (90) days following the end of each calendar quarter for which royalties are due. Each royalty payment shall be accompanied by a report summarizing the total Net Sales during the relevant three-month period, and the calculation of royalties, if any, due thereon pursuant to Section 8.3.

8.6 Taxes. Genentech shall pay any and all taxes levied on account of, or measured by, any payment, including, without limitation, royalties, it receives under this Agreement.

8.7 Termination. If the license granted to Connetics herein is terminated by the Parties, Connetics shall have no obligation to make any milestone or royalty payments to Genentech that has not accrued prior to the effective date of such termination, but shall remain liable for all such payments accruing prior to termination.

8.8 Records and Reporting

(a) Records. Connetics and any sublicensee of Connetics shall keep full, true and accurate books of account containing all particulars which may be necessary for the purpose of showing Net Sales. Said books of account shall be kept at the principal place of business of Connetics or its sublicensee, as the case may be. Said books and the supporting data shall be open at all reasonable times, for three (3) years following the end of the calendar year to which they pertain (and access shall not be denied thereafter, if reasonably available), to the inspection of an independent public accountant retained by Genentech and reasonably acceptable to Connetics (or its sublicensee) for the purpose of verifying Net Sales under this Agreement; subject to the provisions of Section 8.8(c) below.
(b) Reports. Connetics shall within ninety (90) days after the end of each calendar quarter beginning with the quarter of the first commercial sale of Licensed Product in the Field of Use in the Territory by Connetics or its sublicensee, deliver to Genentech a true and accurate report, setting forth such particulars of the business conducted by Connetics and its sublicensees during the preceding quarter as are pertinent to an accounting for Net Sales and deductible expenses under this Agreement. Such reports shall include at least the following: (i) the total gross sales of Licensed Products occurring during that calendar quarter, (ii) the allowable deductions therefrom, (iii) the total Net Sales of Licensed Products occurring during that calendar quarter and (iv) the calculation of royalties, if any, due thereon pursuant to the above Section 8.3.

(c) Auditing. At Genentech’s request and expense, Connetics shall permit a certified public accountant selected by Genentech and acceptable to Connetics to examine, not more than once in any four consecutive calendar quarters during the term of this Agreement, but including one (1) post-termination audit, Connetics’ books of account and records of all sales of Licensed Products by Connetics for the sole purpose of determining the correctness of the reports provided by Connetics under the above Section 8.8(b). If such accountant reasonably determines that the royalties owed by Connetics to Genentech under the above Section 8.3 have been, for any calendar year in total, understated by Connetics, Connetics shall immediately pay all understated royalties, together with interest on such royalties from the date accrued at a rate of *** and shall pay the reasonable costs of the examination if Connetics has understated such royalties by more than ***.

9.0 Representations and Warranties

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
9.1 Disclaimer. Except as expressly provided herein, the Parties disclaim all other representations and warranties, express or implied, including without limitation, WARRANTIES OF COMMERCIAL UTILITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR SCOPE OF GENENTECH PATENT RIGHTS or NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

9.2 Representations and Warranties.

(a) Each party represents and warrants to the other that: (a) it is free to enter into this Agreement; (b) in so doing it will not violate any other agreement to which it is a party; (c) it is currently capable of making the grant of rights described in Sections 2.1(a), (b), (c), (d), 2.2 and 2.4; and (d) it will not enter into any agreement in the future which conflicts with or violates any term or provision of this Agreement. Genentech makes no representation or warranty that all intellectual property rights necessary for Connetics to make, have made, use, sell, offer for sale and import Licensed Products in the Field of Use in the Territory have been granted to Connetics under Section 2.0 of this Agreement.

(b) Connetics further represents and warrants that, prior to the Effective Date of this Agreement, Connetics’ officers (acting under delegated authority of its Board of Directors) have determined that the fair market value of the exclusive license granted to Connetics hereunder is less than $15,000,000 and therefore that the execution and delivery of this exclusive license Agreement, or the performance of the obligations by Genentech or Connetics hereunder, do not require that filings be made under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or under the rules or regulations promulgated thereunder, by Connetics, Genentech, or their respective affiliates or ultimate parent entities, if any.
(c) Genentech represents and warrants to Connetics that as of the Effective Date: (i) to Genentech’s knowledge, it has not received any notice of a claim by a third party for infringement of such third party’s intellectual property relating to the use and practice of the Genentech Knowhow, the Genentech Manufacturing Knowhow, the Genentech Patent Rights or the *** License Rights; and (ii) to the knowledge of Genentech’s patent counsel, there is no issued patent that would be infringed by the practice of the Genentech Knowhow, the Genentech Manufacturing Knowhow or the Genentech Patent Rights as permitted under the license rights granted under Section 2.1; and (iii) it has no knowledge of any actual infringement by any third party in the Field of Use in the Territory of the Genentech Patent Rights.

10.0 Liability

10.1 Limitation of Liability. Neither Party shall be liable to the other for indirect, incidental, special or consequential damages arising out of any of the terms or conditions of this Agreement or with respect to their performance or lack thereof.

10.2 Connetics Indemnification. Connetics shall indemnify, defend and hold harmless Genentech and its affiliates from and against all third party costs, claims, suits, expenses (including reasonable attorneys’ fees) and damages arising out of or resulting from: (a) any willful or negligent act or omission by Connetics relating to the subject matter of this Agreement or (b) the use by or administration to any person of a Licensed Product, Bulk Product or Finished Product that was sold, distributed or otherwise provided to a third party by Connetics or its sublicensees under this Agreement; except where such costs, claims, suits, expenses or damages arose or resulted from any negligent act or omission by

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10.3 Genentech Indemnification. Genentech shall indemnify, defend and hold harmless Connetics, its affiliates and sublicensees from and against all third party costs, claims, suits, expenses (including reasonable attorney’s fees) and damages arising out of or resulting from: (a) any willful or negligent act or omission by Genentech relating to the subject matter of this Agreement; (b) any defect in the manufacture of Bulk Product or Finished Product by Genentech that was not discovered by Connetics; or (c) the use by or administration to any person of a product containing Interferon Gamma sold, distributed or otherwise provided to a third party by Genentech or its sublicensees; except where the foregoing costs, claims, suits, expenses or damages arose or resulted from (i) any negligent act or omission by Connetics or (ii) the use by or administration to any person of a Licensed Product sold, distributed or otherwise provided by Connetics or its sublicensees other than resulting from a defect in the manufacture of such Licensed Product by Genentech, provided that Connetics gives reasonable notice to Genentech of any such claims or action, tenders the defense of such claim or action to Genentech and assists Genentech at Genentech’s expense in defending such claim or action and does not compromise or settle such claim or action without Genentech’s prior written consent.

11.0 Term and Termination
11.1 Term. This Agreement shall commence on the Effective Date of this Agreement and, unless terminated earlier, shall expire at the later to occur of (a) the expiration of the last to expire of any Genentech Patent Rights or (b) twenty (20) years from the Effective Date of this Agreement; provided, however, that in the event that either the *** License or the *** License is terminated, the licenses granted by Genentech to Connetics under the *** License or the *** License shall also terminate. Genentech shall use its Best Efforts to keep the *** License and the *** License in effect during the term of this Agreement, provided, however, that if Connetics declines to pay a *** benchmark payment as outlined in Section 5.2(c) or pay any royalty owed to *** under the *** License for the sales of Licensed Products, then Genentech shall not be obligated to make such payment and Genentech shall have the option, in its sole discretion, to terminate the *** License. One year before the expiration of this Agreement under this Section 11.1, the Parties agree to meet and to discuss in good faith extending the term of this Agreement on terms mutually agreeable to the Parties.

11.2 Termination for Default. If either Party shall default in a material manner with respect to any material provision of this Agreement and the other Party shall have given the defaulting Party written notice of such default, the defaulting Party shall have thirty (30) days to cure such default. If such default is not cured within such thirty (30) day period, the non-defaulting Party shall have the right, upon notice to the defaulting Party and without prejudice to any other rights the non-defaulting Party may have, to terminate this Agreement unless the defaulting Party is in the process of attempting in good faith to remedy such default, in which case, the thirty (30) day cure period shall be extended by an additional thirty (30) days. If Genentech terminates this Agreement pursuant to this Section 11.2,

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Genentech shall automatically have all of the rights set forth in Sections 11.3(a) and (b) of this Agreement. Upon such termination, any sublicenses granted under this Agreement shall not automatically terminate, but instead, Genentech shall have the option to either terminate or continue this Agreement with each sublicensee. If Connetics terminates this agreement pursuant to this Section 11.2, Connetics shall automatically have all of the rights set forth in Section 11.4 of this Agreement. Connetics shall have no right to terminate this Agreement pursuant to this Section 11.2 in the event of Genentech’s failure to supply Bulk Product or Finished Product. In the event of Genentech’s failure to supply Bulk Product or Finished Product, Connetics shall have the rights set forth in the Supply Agreement.

11.3 Genentech’s Rights on Termination

(a) If Genentech terminates this Agreement pursuant to Section 11.2 above, Genentech shall be automatically granted a nonexclusive, sublicenseable, license in the Territory under Connetics Patent Rights and Connetics Knowhow arising from the efforts made by Connetics and its sublicensees hereunder in the research and development of Licensed Products, to make, have made, use, sell, offer for sale or import Licensed Products and shall be automatically granted a right to use all of Connetics’ regulatory submissions made by or on behalf of Connetics for Interferon Gamma and Licensed Products. If Genentech sells a commercial product under the license granted in this Section 11.3 that would, but for the license granted herein, infringe a claim of such Connetics Patent Rights or that is based upon, incorporates or utilizes such Connetics Knowhow, Genentech shall pay Connetics a royalty, under terms and conditions to be mutually agreed upon by the Parties, such royalty to be commensurate with the value contributed by such Connetics Patent Rights and Connetics Knowhow to such commercial product, but in no event shall such royalty
 exceed two percent (2%) of Genentech’s net sales of such commercial product. As used herein, “net sales” shall have the equivalent definition given to Net Sales in Section 1.25 above.

(b) Upon the effective date of termination by Genentech pursuant to Section 11.2 above, Connetics shall promptly provide Genentech with copies of all related documentation regarding Connetics Patent Rights and Connetics Knowhow arising from the efforts made by Connetics and its sublicensees hereunder in the research, development and manufacture of Licensed Products, whether written or electronic, and materials, including biological materials, in the form existing as of the effective date of such termination, reasonably necessary for Genentech to exercise its license rights under Section 11.3(a) above. Such transfer shall be made in a timely and orderly fashion and in a manner such that the value of what is being transferred is preserved in all material respects. Connetics shall promptly take all appropriate and necessary actions, including action before the involved regulatory agency, to effect transfer to Genentech of, and shall also permit Genentech to reference, any FDA submissions, including, without limitation, any PLA or BLA filed with the FDA with respect to Licensed Products. Within ninety (90) days of such assignment and completion of all such appropriate and necessary actions, Genentech will reimburse Connetics for its actual expenses incurred in preparing documentation for filing or referencing the submission and in taking such appropriate and necessary action related to such transfer or referencing.

11.4 Connetics’ Rights on Termination. Should Connetics terminate this Agreement pursuant to Section 11.2 above, Genentech shall grant to Connetics (a) an exclusive, sublicenseable, royalty-bearing license, according to royalty terms described in
Sections 8.3 and 8.4 within the Field of Use in the Territory, under terms and conditions agreed upon by the Parties, under the Genentech Patent Rights and Genentech Knowhow in order to permit Connetics to continue using, selling, offering for sale and importing Licensed Products in the Field of Use in the Territory (excluding, with respect to the fields of scleroderma and infectious disease or condition caused by human papillomavirus, Licensed Products containing any form of interferon gamma other than Genentech Gamma Interferon D3, as that term is defined in the *** License), (b) a non-exclusive, sublicenseable, royalty-bearing license, (conforming to the license grant in Section 2.1 (b) above) according to royalty terms described in Sections 8.3 and 8.4 in the Territory, under terms and conditions agreed upon by the Parties, under the Genentech Patent Rights and Genentech Knowhow in order to permit Connetics to continue using, selling, offering for sale and importing Licensed Products containing any form of interferon gamma other than Genentech Gamma Interferon D3 (as that term is defined in the *** License) in the Territory in the fields of scleroderma and infectious disease or condition caused by human papillomavirus, (c) a non-exclusive, sublicenseable license (the royalty for which is already included in clause (a) above) in the Territory in the fields of scleroderma and infectious disease or condition caused by human papillomavirus, under terms and conditions agreed upon by the Parties, under the *** License Rights in order to permit Connetics to continue using, selling, offering for sale and importing Licensed Products (except those Licensed Products containing *** Gamma Interferon D0) in the field of scleroderma and infectious disease or condition caused by human papillomavirus in the Territory and (d) a non-exclusive sublicenseable license (the royalty for which is already included in clause (a) above) under Genentech Patent Rights and Genentech Manufacturing Knowhow in order to

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11.5 Bankruptcy. Either Party may, in addition to any other remedies available to it by law or in equity, terminate this Agreement, in whole or in part as the terminating Party may determine, by written notice to the other Party in the event the other Party shall have become bankrupt, or shall have made an assignment for the benefit of its creditors or there shall have been appointed a trustee or receiver of the other Party or for all or a substantial part of its property or any case or proceeding shall have been commenced or other action taken by or against the other Party in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereafter in effect and any such event shall have continued for sixty (60) days undismissed, unbonded and undischarged. All rights and licenses granted under to this Agreement by one Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365 (n) of the Bankruptcy Code, licenses of rights to “intellectual property” as defined under Section 101 (56) of the Bankruptcy Code. The Parties agree that the licensing Party under this Agreement shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code in the event of a bankruptcy by the other Party. The Parties further agree that in the event of the commencement of a bankruptcy proceeding by or against one Party under the Bankruptcy Code, the other Party shall be entitled to complete access to any such intellectual property pertaining to the rights granted in the licenses hereunder of the Party by or against whom a bankruptcy proceeding has been commenced and all embodiments of such intellectual property.
11.6 Unilateral Termination. In addition to any other right of termination provided herein, Connetics shall have the right to terminate this Agreement for any reason, with or without cause upon six (6) months’ prior written notice to Genentech. If Connetics terminates this Agreement pursuant to this Section 11.6, Connetics agrees that for the following three (3) years it will not use, sell or acquire from any third party (whether by license or otherwise) any Licensed Product in the Field of Use. If Connetics terminates this Agreement pursuant to this Section 11.6, the licenses granted hereunder shall terminate and Genentech shall automatically have all of the rights set forth in Sections 11.3(a) and (b) of this Agreement.

11.7 Survival of Certain Provisions. Termination of this Agreement for any reason shall not release either Party from any obligation arising prior to the date of termination. The provisions of Sections 1.0, 2.4 (except in the event of termination of this Agreement by Connetics pursuant to Section 11.2), 11.3(a) and (b) (except in the event of termination of this Agreement by Connetics pursuant to Section 11.2), 11.4 (except in the event of termination of this Agreement by Genentech pursuant to Section 11.2), and Articles 5.0, 7.0, 9.0, 10.0, 11.0 (except as provided in this paragraph) and 12.0 shall survive any termination of this Agreement.

12.0 General Provisions

12.1 Notices. All notices which may be required pursuant to this Agreement: (i) shall be in writing, (ii) shall be addressed, in the case of Genentech (except as otherwise specified herein), to the Corporate Secretary at the address set forth at the beginning of this Agreement, and in the case of Connetics, to the Vice President — Intellectual Property at the
address set forth at the beginning of this Agreement, (or to such other person or address as either Party may so designate from time to time), (iii) shall be
mailed, postage-prepaid, by registered mail or certified mail, return receipt requested, or transmitted by courier for hand delivery or transmitted by facsimile
and (iv) shall be deemed to have been given on the date of receipt if sent by mail or on the date of delivery if transmitted by courier or facsimile. Notices by
facsimile may be sent to the following numbers: for Connetics, to (650) 843-2899; for Genentech, to (650) 952-9881.

12.2 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the state of California (other than its choice of
law principles).

12.3 Entire Agreement. This Agreement is the entire agreement between the Parties, and there are no prior written or oral promises or representations
not incorporated herein or therein, except that certain Confidentiality Agreement between the Parties dated January 9, 1997 which shall remain in full force
and effect. This Agreement shall supersede and replace the Prior Agreement in its entirety, and the Prior Agreement shall be terminated automatically as of the
Effective Date. No amendment or modification of the terms of this Agreement shall be binding on either Party unless reduced to writing and signed by an
authorized officer of the Party to be bound.

12.4 Binding Effect and Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective permitted
successors and assigns. This Agreement shall not be assignable by either Party without the other’s prior written consent, provided however, that either Party
may assign this Agreement, without the other Party’s written consent but after providing thirty (30) days prior written notice to the other Party, to any
successor pursuant to a consolidation or merger of such Party with or into
any other corporation or corporations that results in a change of greater than 50% of the voting control of such Party, or a sale, conveyance or disposition of all or substantially all of the assets of such Party or the effectuation by such Party of a transaction or series of related transactions in which more than 50% of the voting power of such Party is disposed of.

12.5 Waiver. The waiver by a Party hereto of any breach of or default under any of the provisions of this Agreement or the failure of a Party to enforce any of the provisions of this Agreement or to exercise any right thereunder shall not be construed as a waiver of any other breach or default or as a waiver of any such rights or provisions hereunder.

12.6 Severability. If any part of this Agreement shall be invalid or unenforceable under applicable law, such part shall be ineffective only to the extent of such invalidity or unenforceability, without in any way affecting the remaining parts of this Agreement. In addition, the part that is ineffective shall be reformed in a mutually agreeable manner so as to as nearly approximate the intent of the Parties as possible.

12.7 Publicity. Connetics and Genentech agree that, except as may otherwise be required by applicable laws, regulations, rules, or orders, including the disclosure requirements of the Securities and Exchange Commission ("SEC"), no information concerning this Agreement and the transactions contemplated herein (except information which is already in the public domain) shall be made public by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, with respect to complying with the disclosure requirements of the SEC, in connection with any required SEC filing of this Agreement by Connetics, Connetics shall seek confidential treatment of portions of this Agreement from the SEC and Genentech shall have the right to review and comment on such an application for confidential treatment prior to its being filed with the SEC. Genentech
shall provide its comments, if any, on such application as soon as practicable and in no event later than seven (7) days after such application is provided to Genentech. To assist Connetics in its compliance with SEC disclosure obligations, Genentech shall provide to Connetics, within fourteen (14) days of the Effective Date, electronic copies of this Agreement (and all exhibits hereto) and the Supply Agreement. In addition, notwithstanding the foregoing, Connetics shall have the right to disclose information concerning this Agreement and the transactions contemplated herein to its legal representatives, advisors, prospective investors, investors, third party auditors, sublicensees and prospective sublicensees hereunder to the extent reasonably necessary and under obligations of confidentiality no less stringent than those provided for in Article 7.0.

12.8 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original for all purposes, but all of which together shall constitute one and the same instrument.

12.9 Force Majeure. Neither Party shall be liable to the other for its delay or failure to perform under this Agreement or shall have any right to terminate this Agreement for any such delay or failure in performance attributable to any act of God, flood, fire, explosion, strike, lockout, labor dispute, casualty or accident, war, revolution, civil commotion, act of public enemies, blockage or embargo, injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any government or subdivision, authority or representative of any such government, or any other cause beyond the reasonable control of such Party, if the Party affected shall give prompt notice of any such cause to the other Party. The Party giving such notice shall thereupon be excused from such of its obligations, hereunder for the period of time that it is so disabled.
12.10 Headings. Headings are for the convenience of reference only and shall not control the construction or interpretation of any of the provisions of this Agreement.

12.11 No Partnership. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer-employee, or joint venture relationship between the Parties.

[Signature page follows]

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed by its duly authorized representative(s) as of the date set forth above.

GENENTECH, INC.

By: /s/ Nicholas J. Simon
Name: Nicholas J. Simon
Title: Vice President, Business and Corporate Development

CONNETICS CORPORATION

By: /s/ Thomas Wiggans
Name: Thomas Wiggans
Title: President/CEO
## Exhibit A

### Patent Applications and Patents Included in Genentech Patent Rights

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Exhibit B

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*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.

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Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
Exhibit D

Third Part Sponsored Studies

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Exhibit E
Clinical Development Milestones

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The following information/reports will be provided to Genentech in a timely manner:

- FDA Meeting Minutes
- IND(s)
- Initial
- Updates (if applicable)
- Annual Report(s)
- Investigator Brochure(s)
- Clinical Studies:
  - Protocol(s)
  - Prior to FDA submission
  - First Patient-In (FPI)
  - First Patient-Out (FPO)
  - Last Patient-In (LPI)
  - Last Patient-Out (LPO)
- Serious Adverse Event (SAE) Summary
- Clinical Study Interim Analysis and Update(s) (if applicable)
- Go/No-Go Decision Minutes
- Clinical Study Final Report(s)
- Draft
- Final Copy
Royalties are payable under the *** License, as follows (capitalized terms shall have the meanings defined in the *** License): a *** royalty is payable on Net Sales of gamma interferon in Approved Countries in the Territory for the prophylaxis or treatment of atopic dermatitis and/or steroid-dependent asthma, where there is substantial protection from an issued Licensed Patent for the approved indication and where the Licensee has enjoyed Market Exclusivity. The royalty rate is *** on Net Sales in the Licensed Field in Approved Countries where the Licensee enjoyed Market Exclusivity but where there is no substantial patent protection, or while the Licensed Patent applications covering the indication are still pending, provided that such applications have been diligently prepared, filed and maintained. The royalty rates described above are reduced by *** for Approved Countries where the Licensee has not enjoyed Market Exclusivity.

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Prior to the Transfer Date, as defined in Section 1.29 of this Agreement, the following activities must be completed by the appropriate Party as described below:

I. Regulatory Requirements

1. FDA License – Connetics must obtain all licenses, including license numbers, required for the sale of Actimmune for CGD by Connetics. Connetics shall also obtain a NDC number.

2. PLA/IND Transfer – Genentech shall transfer to Connetics the PLA and IND for CGD on file with the FDA.

3. Connetics must obtain FDA review and approval, as required by law or regulation, for Connetics’ labels, product insert and packaging for sale of Actimmune for CGD.

4. Genentech shall transfer its safety information to Connetics for Actimmune, as provided in Section 2.5(g) of this Agreement. Connetics shall establish a safety database system for Actimmune, such that as of the Transfer Date, Connetics shall be responsible for all safety-related requirements under FDA regulations, including the reporting of adverse events.

5. Prior to the Transfer Date, Connetics shall establish all procedures, controls and other methods and capabilities needed in order to comply with all requirements, laws and regulations applicable to the use, distribution and sale of Actimmune for CGD.

II. Quality Control, Product Testing

1. To the extent that Connetics is required by law or regulation to conduct any quality control, quality assurance and/or stability testing of Actimmune sold for CGD, in addition to any such testing to be conducted by Genentech pursuant to the Supply Agreement, Connetics shall establish procedures and obtain regulatory approval to do so prior to the Transfer Date.

III. Uninsured Patient Program

Connetics shall have established an uninsured patient program, including procedures for determining patient eligibility. Genentech shall transfer to Connetics its existing information regarding such patients prior to the Transfer Date, to the extent it has received consent from such patients to do so. Connetics shall notify Genentech prior to the Transfer Date which of the patients participating in Genentech’s uninsured patient program, and for which Genentech has transferred information, shall receive drug under Connetics’ uninsured patient program.
IV. Product Distribution and Sale

1. Connetics shall establish product distribution and inventory systems for Actimmune. Genentech will provide to Connetics the name of its current distributor.

2. Connetics shall establish systems and personnel required to address customer inquiries, medical information requests and product returns.
AMENDMENT NO. ONE
TO
LICENSE AGREEMENT

THIS AMENDMENT NUMBER ONE TO LICENSE AGREEMENT FOR INTERFERON GAMMA ("Amendment") is entered into effective December 28, 1998, between Genentech, Inc. ("Genentech") and Connetics Corporation ("Connetics"). Terms not otherwise defined in this Amendment shall have the meanings as defined in the License Agreement.

RECITALS

A. The parties have previously entered into a License Agreement effective May 5, 1998, relating to interferon gamma (the "License Agreement"), together with a Stock Purchase Agreement of even date (the "Stock Agreement").

B. Pursuant to Section 2.3(c) of the License Agreement, Connetics had the right to sublicense the Agreement to InterMune, and has in fact entered into a sublicense to that effect dated August 21, 1998.

C. Pursuant to Section 8.1 of the License Agreement, and the terms of the Stock Agreement, Connetics agreed to issue additional stock to Genentech if certain conditions were not met by December 28, 1998, and the parties anticipate that those conditions will not be met by that date.

D. The parties desire to amend the License Agreement effective as of the date first written above, on the terms forth in this Amendment, and simultaneously with a corresponding Amendment Number One to the Stock Purchase Agreement ("Stock Agreement Amendment").

NOW THEREFORE, the parties agree as follows:

AGREEMENT

1. Section 8.1 of the License Agreement is hereby amended to read in its entirety as follows:

   8.1 Up-front Payment. Connetics shall issue to Genentech upon the Original Closing Date (as defined in the Stock Agreement) shares of Connetics Common Stock ("Original Issuance Shares" as defined in the Stock Agreement) with a fair market value equal to two million dollars ($2,000,000), on the terms and conditions set forth in the Stock Agreement. If on the Notification Date or, if later, the Second Closing Date (each as defined in the Stock Agreement Amendment), the aggregate market value of the Original Issuance Shares (based on the Second Issuance Price, as defined in the Stock Agreement Amendment) is less than $4,000,000, then Connetics shall issue to Genentech on the Second Closing Date that number of additional shares of its Common Stock (the “Second Issuance Shares”) equal to the lesser of: (i) the number of shares necessary to increase the aggregate market value of the Original Issuance Shares (based on the Second Issuance Price) and the Second Issuance Shares (based on the Second Issuance Price) to $4,000,000; or (ii) the number of shares
(rounded to the nearest whole number) necessary to increase the aggregate number of shares of Connetics Common Stock held by Genentech (exclusive of any shares that Genentech has purchased from parties other than Connetics) to 9.9% of Connetics’ total outstanding shares of Common Stock as of the close of business on the Notification Date or the Second Closing Date, if later. In lieu of all or any portion of the Second Issuance Shares that Connetics is obligated to issue to Genentech on the Second Closing Date, Connetics may elect to pay Genentech the cash value of such Second Issuance Shares (based on the Second Issuance Price). The Original Closing of the stock issuances shall take place as described in the Stock Agreement and the Second Closing of the stock issuances shall take place as described in the Stock Agreement Amendment. In the event that Connetics does not issue to Genentech all of the Second Issuance Shares or the cash value of the Second Issuance Shares, Genentech may, in addition to other remedies available to it by law or in equity, immediately terminate this Agreement and the licenses granted to Connetics under this Agreement. Such termination by Genentech of the Agreement and the licenses hereunder does not discharge Connetics’ obligation to issue all of the Second Issuance Shares or to pay to Genentech the cash value of the Second Issuance Shares. The up-front payment shall not be creditable against any royalty payments owed by Connetics under Sections 8.3 and 8.4 of this Agreement.

2. To the extent necessary, the remaining provisions of the License Agreement are amended to reflect the revised definitions of Second Closing Date and Second Issuance Shares, as modified by the Stock Agreement Amendment.

3. The remainder of the License Agreement, including the exhibits to that Agreement (except the Stock Agreement, to the extent modified by the Stock Agreement Amendment), will continue in full force and effect as though fully set forth in this Amendment.

IN WITNESS WHEREOF, the parties have executed this Amendment Number One to License Agreement as of the date first written above.

Genentech, Inc.
By:/s/ W. D. Young KM
William D. Young
Chief Operating Officer

Connetics Corporation
By:/s/ T. Wiggans
Thomas G. Wiggans
President and Chief Executive Officer
AMENDMENT NO. TWO
TO
LICENSE AGREEMENT

THIS AMENDMENT NUMBER TWO TO LICENSE AGREEMENT FOR INTERFERON GAMMA (“Amendment”) is entered into effective January 15, 1999, by and between Genentech, Inc. (“Genentech”) and Connetics Corporation (“Connetics”).

RECITALS

A. The Parties have previously entered into that certain License Agreement for Interferon Gamma, dated May 5, 1998, as amended on December 23, 1998 (the “License Agreement”).

B. Pursuant to Section 2.3(c) of the License Agreement, Connetics has the right to sublicense certain of its rights under the Agreement to InterMune Pharmaceutical, Inc. (“InterMune”), and has in fact entered into a sublicense to that effect dated August 21, 1998.

C. On December 3, 1998, the Parties entered into a Letter Agreement to document the intent and agreement of Connetics and Genentech with respect to additional terms governing the transfer and distribution of Interferon Gamma-1B, pending the preparation of an amendment to the License Agreement.

D. The Parties now desire to enter into a definitive amendment to the License Agreement, effective as of the date first written above, to permit a limited distribution of Interferon Gamma-1B by Connetics or its sublicensee under Genentech labels and to add other additional terms governing the transfer and distribution of Interferon Gamma-1B.

NOW THEREFORE, the Parties hereby agree as follows:

AGREEMENT

1. Terms not otherwise defined in this Amendment shall have the meanings defined in the License Agreement.

2. Section 1.29 of the License Agreement is hereby deleted and replaced in its entirety as follows:

   1.29 “Transfer Date” shall mean January 15, 1999, unless otherwise mutually agreed to in writing by the Parties.
3. A new Section 1.30 is added to the License Agreement to read in its entirety as follows:

1.30 “Connetics Product” shall mean Finished Product under the ACTIMMUNE® trademark and labeled under the name of Connetics or its sublicensee. For clarification, all terms and conditions of this Agreement that apply to Finished Product shall also apply to Connetics Product.

4. A new Section 1.31 is added to the License Agreement to read in its entirety as follows:

1.31 “Distribution Period” shall mean the period of time beginning January 15, 1999 and ending on the earlier of: (a) the first date on which Genentech supplies InterMune with Connetics Product or (b) sixty (60) days after InterMune’s receipt of a license from the FDA to sell Interferon Gamma-1B for CGD.

5. A new Section 1.32 is added to the License Agreement to read in its entirety as follows:

1.32 “Genentech Finished Product” shall mean Genentech’s inventory of Interferon Gamma-1B under the ACTIMMUNE® trademark and labeled under Genentech’s name. For clarification, Genentech Finished Product is a Licensed Product under this Agreement.

6. A new Section 1.33 is added to the License Agreement to read in its entirety as follows:

1.33 “Genentech Bulk Product” shall mean Genentech’s inventory of Interferon Gamma-1B bulk protein existing as of the Transfer Date.

7. A new Section 1.34 is added to the License Agreement to read in its entirety as follows:

1.34 “Genentech Product” shall mean, together, Genentech Finished Product and Genentech Bulk Product.

8. A new Section 1.35 is added to the License Agreement to read in its entirety as follows:

1.35 “Fully Burdened Manufacturing Cost” shall mean ***, which shall be comprised of the sum of: ***

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
9. A new Section 1.36 is added to the License Agreement to read in its entirety as follows:

1.36 “Third Party Manufacturing Royalties” shall mean all royalties paid or incurred by Genentech to third parties under licenses taken by Genentech with respect to patents or patent applications that, but for such license(s), would be infringed by the manufacture, use, sale, offer for sale or importation of Genentech Finished Product or Genentech Bulk Product, which royalties are based on the manufacture and sale of Genentech Finished Product or Genentech Bulk Product by Genentech (or its contract manufacturer) or by Connetics or its sublicensees (or a contract manufacturer on their behalf). Genentech shall notify Connetics in writing during the term of this Agreement if it becomes aware of any Third Party Manufacturing Royalties.

10. A new Subsection 2.5(k) is added to the License Agreement to read in its entirety as follows:

2.5(k) Provided that all the activities listed on Exhibit H attached hereto are completed, Genentech also shall transfer to Connetics or its sublicensee on the Transfer Date all responsibility for the distribution, sales and product support of Genentech Finished Product, in the Territory, for the treatment of infections associated with CGD, subject to the provisions of Section 4.3 below and the following terms and conditions:

(i) Product support of Genentech Finished Product shall include, without limitation, all financial services, all reporting required by federal and state law or regulation, professional services, customer inquiries, product returns, government chargebacks, product refunds, and patient assistance programs, except for the processing of state Medicaid invoices and certain product returns, as provided in Subsections 2.5(k)(iii) and (iv) below.

(ii) Connetics or its sublicensee shall sell and distribute Genentech Finished Product only during the Distribution Period, after which time Connetics or its sublicensee shall market, sell and distribute Connetics Product, or other Finished Product, for CGD. Notwithstanding the foregoing, for a period of ten (10) business days after the last day of the Distribution Period, Connetics or its sublicensee may continue to sell and distribute its existing inventory of Genentech Finished Product in order to reduce or exhaust
such existing inventory. Under no circumstances, however, will Genentech be required to manufacture, fill, label, package, or otherwise supply Genentech Finished Product to Connetics or its sublicensees after the end of the Distribution Period. After the Distribution Period Connetics or its sublicensees shall retain full responsibility, and provide all product support, for all Genentech Product sold or distributed by Genentech, Connetics or its sublicensees, prior to, during and after the Distribution Period, including without limitation, Genentech Product in distribution channels.

(iii) Notwithstanding the above, Genentech shall remain responsible for processing state Medicaid invoices for Genentech Finished Product, in accordance with this subsection, during the Distribution Period and for that period of time after the Distribution Period during which states continue to send Medicaid rebate invoices for Genentech Finished Product sold under the Genentech NDC label number 50242. Within fifteen (15) days after the end of each calendar quarter, Connetics or its sublicensee shall supply Genentech with a report of its Average Manufacturer Price (“AMP”) and Best Price (“BP”), as defined in the U.S. Omnibus Budget Reconciliation Act of 1990 (“OBRA 90”), for Genentech Finished Product for such quarter, and detailed calculations determining such AMP and BP. The AMP, BP and supporting calculations shall be based on the carton price for Genentech Finished Product. Genentech shall report such quarterly AMP and BP to the Health Care Finance Administration as required by law and regulation, and will also process state Medicaid rebate invoices received for Genentech Finished Product. Genentech will pay, adjust or dispute the state Medicaid rebate invoices as permitted under OBRA 90. Within sixty (60) days of receipt of an invoice from Genentech, Connetics or its sublicensee will reimburse Genentech the full amounts of Medicaid rebates paid by Genentech. Genentech will have the right to examine, but not more than once every calendar year, the books of account and records of Connetics and its sublicensees for the purpose of determining the correctness of the quarterly reports provided by Connetics or its sublicensees under this subsection. If Genentech reasonably determines that any such reports(s) were incorrect, Connetics shall pay Genentech’s costs of correcting its reports to federal agencies and will also pay any penalties or fees associated with such incorrect reporting.

(iv) As of the Transfer Date, Connetics or its sublicensees will be responsible for processing returns and related credits for all Finished Product, except that Genentech will process credits for returns of Genentech Finished Product if Genentech receives a returned Genentech Finished Product from a third party. Within sixty (60) days of receipt of an invoice from Genentech, Connetics or its sublicensees will reimburse Genentech for such return credits processed by Genentech.
(v) Connetics or its sublicensees shall be responsible for all government chargebacks for Genentech Finished Product sold by wholesalers to customers on and after the Transfer Date, and for all government chargebacks for all Connetics Product and other Finished Product sold by Connetics and its sublicensees.

(vi) Connetics and its sublicensees shall not actively market or promote Interferon Gamma-1B during the Distribution Period and while selling or distributing Genentech Finished Product. During the Distribution Period, Connetics and its sublicensees shall not distribute any notice, publication or make any presentation to any third party regarding Interferon Gamma-1B without Genentech’s prior review of such notice, publication or presentation, and receipt of Genentech’s prior written consent. Connetics and its sublicensees shall not sell Genentech Finished Product at a price higher than that charged by Genentech on January 14, 1999.

11. A new Section 2.5(l) is added to the License Agreement to read in its entirety as follows:

2.5(l) Connetics agrees that, as of the Transfer Date and under the terms and conditions below, it or its sublicensee will supply Genentech Finished Product to those certain patients in the U.S. to whom Genentech has an existing contractual or regulatory obligation to supply Interferon Gamma-1B, including prior clinical study patients. In addition, Connetics or its sublicensee will supply Genentech Finished Product to Hoffman-LaRoche Canada Limited (“Roche Canada”) for distribution to patients to whom there is a contractual or regulatory obligation to supply Interferon Gamma-1B. Connetics also agrees that it or its sublicensee will supply Genentech Finished Product free of charge to those oncology study patients (including National Cancer Institute oncology clinical trial patients) who are continuing to receive Interferon Gamma-1B, as soon as reasonably possible. After the end of the Distribution Period, Connetics or its sublicensee shall supply Connetics Product, or other Finished Product, to such patients and to Roche Canada in the same quantities. No other right or license is implied or granted to Connetics or its sublicensees to distribute Genentech Finished Product, or any other Licensed Product, outside the Field of Use or outside the Territory.

(i) To supply the patients and Roche Canada as described above, Connetics or its sublicensee shall pay a price for such Genentech Finished Product, and such Connetics Product and other Finished Product supplied by Genentech, equal to percent (*** ) of Genentech’s Fully Burdened Manufacturing Cost, plus *** of Third Party Manufacturing.

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
Royalties attributable to the manufacture or distribution of such Genentech Finished Product or other Finished Product.

(ii) For U.S. CGD clinical study patients that do not qualify for Connetics’ (or its sublicensee’s) indigent patient program, Connetics (or its sublicensee) shall supply, at its own cost, Genentech Finished Product and Finished Product to such patients free of charge for a period of time ending not later than December 31, 1999. Connetics (or its sublicensee) shall notify such patients that such drug shall not continue to be supplied free of charge by Genentech, Connetics or its sublicensee, and Connetics or its sublicensee shall use its best efforts to terminate such supply of drug before December 31, 1999, after reasonable prior notice to such patients. ***

(iii) Roche Canada will reimburse Connetics, or its sublicensee, for its cost of supplying such Genentech Finished Product and Connetics Product to the patients in Canada under a separate agreement to be negotiated and executed by Roche Canada and Connetics.

(iv) Connetics, or its sublicensee, will supply Genentech Finished Product and Finished Product to the oncology patients without charge to Genentech or to such patients. If, however, Genentech has not extended the Field of Use of this Agreement to the field of oncology within six (6) months of the Effective Date of this Amendment No. 2, then Genentech will reimburse Connetics, or its sublicensee, for the cost of such Genentech Finished Product and Finished Product during such six month period. If Genentech thereafter extends the Field of Use to oncology, then as of the effective date of such extension Connetics or its sublicensee will provide Finished Product to such patients without charge to Genentech or to such patients. If Genentech does not extend the Field of Use to oncology, Connetics or its sublicensee will continue to supply such oncology patients, but Genentech will reimburse Connetics, or its sublicensee, for such drug in an amount equal to one hundred percent (100%) of the price paid to Genentech for such Genentech Finished Product and Finished Product and the direct administrative and distribution costs of providing such drug to such patients.

12. A new Section 4.3 is added to the License Agreement to read in its entirety as follows:

4.3(a) Genentech shall sell to Connetics, or its sublicensee, Genentech’s existing inventory of Genentech Product for commercial sale

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solely for the treatment of infections associated with CGD. Connetics shall pay a price for such Genentech Product equal to *** percent (***) of Genentech’s Fully Burdened Manufacturing Cost, plus *** of Third Party Manufacturing Royalties attributable to the manufacture or sale of such Genentech Product.

(b) Genentech shall deliver Genentech Finished Product to Connetics to a single destination in the United States chosen by Connetics, by carrier identified by Connetics. Title and risk of loss as to all Genentech Finished Product shall pass to Connetics at point of origin (FOB Genentech). Connetics shall be responsible for all freight, freight brokerage, insurance and other costs associated with shipping Genentech Finished Product hereunder. As soon as reasonably possible after each shipment of Genentech Finished Product, Genentech shall forward to Connetics all customary documents concerning the shipment, including Genentech’s invoice relating to such shipment. To the extent possible, a certificate of analysis will be included in each shipment. Where it is not possible to include a certificate of analysis with a shipment, Genentech shall furnish the same to Connetics as soon as reasonably possible.

(c) Payment by Connetics shall be made within sixty (60) days after Connetics’ receipt of Genentech’s invoice for the supply of GenentechFinished Product. All payments to Genentech by Connetics under this Agreement shall be made in United States dollars by wire transfer (or such other reasonable means as Genentech may direct) to such United States bank account as Genentech may direct. If a wire transfer is to be made, Connetics shall provide notice at least five (5) days prior to the date of transfer of the amount of payment and the date good funds will be received. Such notice should be given to the Treasurer of Genentech at the address set forth at the beginning of this Agreement or such other address as Genentech may subsequently direct.

(d) Genentech shall use its best efforts to maintain its Fully Burdened Manufacturing Cost for Genentech Finished Product at or below the benchmark costs of *** dollars (***) per vial of Genentech Finished Product (the “Benchmark Costs”). All the provisions of Section 2.6(e) of that certain Supply Agreement, dated May 5, 1998, between Genentech and Connetics, shall apply to such Benchmark Costs herein.

(e) All transfer of Genentech Finished Product to Connetics or its sublicensee hereunder shall be subject to the provisions hereof and shall not be subject to the terms and conditions contained on any purchase order or confirmation by Genentech, except insofar as any such purchase order or confirmation establishes: (i) the quantity and form of Genentech Product; (ii) the shipment date; (iii) the shipment routes and destinations; or (iv) the carrier.

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.

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13. This Amendment supersedes in its entirety the Letter Agreement dated December 3, 1998.

14. All other terms and provisions of the License Agreement, including all exhibits to that Agreement, will continue in full force and effect as though fully set forth in this Amendment. Nothing in this Amendment shall be construed as affecting Connetics’ obligations to be liable and responsible for the performance of all of the obligations of Connetics and its sublicensees under the License Agreement.

IN WITNESS WHEREOF, the parties have executed this Amendment Number Two to License Agreement as of the date first written above.

Genentech, Inc.

By: /s/ Nicholas J. Simon
Name: Nicholas J. Simon
Title: Vice President, Business and Corporate Development

Connetics Corporation

By: /s/ Thomas G. Wiggans
Name: Thomas G. Wiggans
Title: President and Chief Executive Officer

Acknowledged and agreed as to InterMune’s rights and obligations hereunder as Connetics’ sublicensee under the License Agreement:

InterMune Pharmaceuticals, Inc.

By: /s/ Scott Harkonen
Scott Harkonen, M.D.
President

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AMENDMENT NO. THREE TO LICENSE AGREEMENT

THIS AMENDMENT NUMBER THREE TO LICENSE AGREEMENT FOR INTERFERON GAMMA (“Amendment”) is entered into effective April __, 1999 (the “Amendment Effective Date”), by and between Genentech, Inc. (“Genentech”) and Connetics Corporation (“Connetics”). Genentech and Connetics may each be referred to herein as a “Party” and jointly as the “Parties.”

RECITALS

A. The Parties have previously entered into that certain License Agreement for Interferon Gamma, dated May 5, 1998, as amended on December 23, 1998 and on January 15, 1999 (the “License Agreement”).

B. Pursuant to Section 2.3(c) of the License Agreement, Connetics has the right to sublicense certain of its rights under the Agreement to InterMune Pharmaceuticals, Inc. (“InterMune”), and has in fact entered into such sublicense to that effect dated August 21, 1998.

C. The Parties have entered into that certain letter agreement dated January 5, 1999 and revised on March 1, 1999 (the “Letter Agreement”), documenting the intent and agreement of Connetics and Genentech with respect to certain additional rights to be granted to Connetics and its sublicensees under the Genentech License, pending the preparation of an amendment to the License Agreement.

D. In consideration of such additional rights, ***

E. The Parties now desire to enter into a definitive amendment to the License Agreement, as of the Amendment Effective Date, through which Genentech shall grant, and Connetics and InterMune shall accept, such certain additional rights under the License Agreement.

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants and conditions herein contained, and intending to be legally bound hereby, the Parties mutually agree as follows:

1. Terms not otherwise defined in this Amendment shall have the meanings defined in the License Agreement.

2. A new Section 1.7.1 is hereby added to read in its entirety as follows:

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
1.7.1 “Combination Product Adjustment” shall mean the following: in the event that a Licensed Product is sold in the form of a combination product containing one or more active ingredients or components in addition to such Licensed Product, Net Sales for such combination product will be adjusted by multiplying actual Net Sales of such combination product by the fraction \( \frac{A}{A + B} \) where \( A \) is the invoice price of the Licensed Product, if sold separately, and \( B \) is the invoice price of any other active ingredient(s) or component(s) in the combination, if sold separately. If, on a country-by-country basis, the other active ingredient(s) or component(s) in the combination are not sold separately in said country, Net Sales shall be calculated by multiplying actual Net Sales of such combination product by the fraction \( \frac{A}{C} \) where \( A \) is the invoice price of the Licensed Product if sold separately, and \( C \) is the invoice price of the combination product. If, on a country-by-country basis, neither the Licensed Product nor the other active ingredient(s) or component(s) of the combination product is sold separately in said country, Net Sales allocable to the Licensed Product shall be determined by mutual agreement reached in good faith by the Parties based on an equitable method of determining such Net Sales that, among other considerations, takes into account, on a country-by-country basis, variations in potency, the relative contribution of each active ingredient or component in the combination product and the relative value to the end-user of each active ingredient or component.

3. Section 1.12 of the License Agreement is hereby deleted and replaced in its entirety as follows:

1.12 “Field of Use” shall mean the administration to humans of Licensed Protein Product for the treatment or prevention of any human disease or condition, ***

. Each “indication” listed on Exhibit E attached hereto shall be referred to herein individually as an “Area of the Field of Use” and collectively as “Areas of the Field of Use.”

4. A new Section 1.15.1 is hereby added to the Agreement to read in its entirety as follows:

1.15.1 “Gene Therapy Field of Use” shall mean the administration to humans of Licensed Gene Product for Gene Therapy for the treatment or prevention of any human disease or condition, ***

5. Section 1.18 of the License Agreement is hereby deleted and replaced in its entirety as follows:

1.18 “Genentech Patent Rights” shall mean all patents and patent applications and any patents issuing therefrom, together with any extensions, reissues, reexaminations, substitutions, renewals, divisions, continuations and continuations-in-part thereof:

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
(a) that are owned or controlled by Genentech presently or hereafter, during the term of this Agreement, and under which Genentech is free
to license or sublicense; and

(b) to the extent they claim or directly relate to: (i) Interferon Gamma or the manufacture or use of Interferon Gamma in the Field of Use, or
(ii) IG Nucleotide Sequence or the manufacture or use of IG Nucleotide Sequence in the Gene Therapy Field of Use;

including, without limitation, the patent rights granted under that certain license agreement between Genentech and Children’s Medical Center
Corporation, dated July 16, 1990 (the “CMCC License”), but specifically excluding any rights granted to Genentech under the Biogen License.
Genentech Patent Rights shall include, without limitation, the patents and patent applications listed in Exhibit A attached hereto.
Notwithstanding the foregoing, Genentech Patent Rights shall exclude any rights Genentech acquires after the Effective Date under third-party
license agreements, with the exception of those rights acquired under the CMCC License, unless and until the Parties mutually agree on terms
and conditions for the sublicense of such rights from Genentech to Connetics.

6. A new Section 1.20.1 of the License Agreement is hereby added to read in its entirety as follows:

1.20.1 “IG Nucleotide Sequence” shall mean any DNA or RNA sequence encoding Interferon Gamma.

7. Section 1.22 of the License Agreement is hereby deleted and replaced in its entirety as follows:

1.22 “Licensed Product” shall mean, collectively:

(a) Any pharmaceutical formulation containing Interferon Gamma, whether alone or together with or incorporated into any other substance
or product or material or device, whether active or not, and which (i) but for the licenses granted hereunder, the manufacture, use, sale, offer for
sale or importation of which in the Territory would infringe or contribute to the infringement of the Genentech Patent Rights in the Territory, or
(ii) is based upon or incorporates or utilizes Genentech Knowhow (a “Licensed Protein Product”); and

(b) Any pharmaceutical formulation containing the IG Nucleotide Sequence, whether alone or together with or incorporated into any other
substance or product or material or device, whether active or not, and which but for the licenses granted hereunder, the manufacture, use, sale,
offer for sale or importation of which in the Territory would infringe or contribute to the infringement of the Genentech Patent Rights in the
Territory (a “Licensed Gene Product”).

8. The following two sentences are hereby added to the end of Section 1.25:

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shall also be deducted from the gross invoiced sales prices charged for such Licensed Products in determining Net Sales for such Licensed Products. In the event that a Licensed Product is sold in the form of a combination product containing one or more active ingredients or components in addition to such Licensed Product, Net Sales for such combination product will be calculated in accordance with the Combination Product Adjustment.”

9. Section 1.28 of the License Agreement is hereby deleted and replaced in its entirety as follows:

1.28 “Territory” shall mean the United States of America, and its territories and possessions, and Japan.

10. A new Section 1.37 is hereby added to the License Agreement to read in its entirety as follows:

1.37 “Third Party Product Rights” shall mean any rights licensed or sublicensed to any third party by Genentech as of the Effective Date to use, manufacture or sell (a) Interferon Gamma, (b) the IG Nucleotide Sequence or (c) any pharmaceutical formulation containing either or both of Interferon Gamma and the IG Nucleotide Sequence, whether alone or together with or incorporated into any other substance or product or material or device, whether active or not; ***

11. Section 2.1 of the License Agreement is hereby deleted and replaced in its entirety as follows:

2.1 Patent and Knowhow License Grants.

(a) Genentech hereby grants to Connetics an exclusive license, even as to Genentech, under Genentech Patent Rights and under Genentech Knowhow to use, sell, offer for sale and import (but not to make or have made) Licensed Protein Products in the Field of Use in the Territory (excluding Japan), (excluding, with respect to the fields of (i) scleroderma and (ii) infectious disease or condition caused by human papillomavirus), Licensed Protein Products containing any form of Interferon Gamma other than Genentech Gamma Interferon A3 (as that term is defined in the Biogen License). Notwithstanding the foregoing, Genentech reserves the right to use (but not to import, offer for sale or sell) Licensed Protein Products within the Field of Use solely for noncommercial research purposes.

(b) Genentech hereby grants to Connetics a non-exclusive license under Genentech Patent Rights and under Genentech Knowhow to use, sell, offer for sale and import (but not to make or have made) Licensed Protein Products containing any form of Interferon Gamma other than Genentech Gamma

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Interferon Δ3 (as that term is defined in the Biogen License) in the Territory (excluding Japan) in the fields of: (i) scleroderma and (ii) infectious disease or condition caused by human papillomavirus.

(c) Genentech hereby grants to Connetics a non-exclusive sublicense under the Biogen License Rights to use, sell, offer for sale and import Licensed Protein Products (excluding Licensed Protein Products containing Biogen Gamma Interferon Δ0 (as that term is defined in the Biogen License)) in the Territory (excluding Japan) in the fields of scleroderma and infectious disease or condition caused by human papillomavirus.

(d) Genentech hereby grants to Connetics a non-exclusive license under Genentech Patent Rights to make or have made in the Territory (excluding Japan) Licensed Protein Products for use or sale in the Field of Use in the Territory (excluding Japan).

(e) Genentech hereby grants to Connetics a non-exclusive license under Genentech Patent Rights and Genentech Knowhow to use non-human animal species derived homologues of Interferon Gamma (“Non-human Interferon Gamma”) solely for non-commercial research purposes to support the Field of Use in the Territory (excluding Japan). Genentech hereby grants to Connetics a non-exclusive license under Genentech Patent Rights to use non-human animal species derived homologues of IG Nucleotide Sequence (“Non-human Interferon Gamma-encoding IG Nucleotide Sequence”) solely for non-commercial research purposes to support the Gene Therapy Field of Use in the Territory (excluding Japan).

(f) Genentech hereby grants to Connetics a co-exclusive license under Genentech Patent Rights to use, make, have made, import, offer for sale and sell Licensed Gene Products in the Gene Therapy Field of Use in the Territory (excluding Japan). Notwithstanding the foregoing, Genentech reserves the right to use (but not to import, offer for sale or sell) Licensed Gene Products within the Gene Therapy Field of Use solely for non-commercial research purposes. As used in this subsection (f), “co-exclusive” shall mean that (i) Genentech shall not grant a license to any party other than Connetics to use, make, have made, import, offer for sale or sell Licensed Gene Products in the Gene Therapy Field in the Territory (excluding Japan) *** , and (ii) Genentech shall not authorize or approve any grant or assignment *** .

(g) (i) Genentech hereby grants to Connetics an exclusive license, even as to Genentech, under Genentech Patent Rights and under Genentech Knowhow, in Japan to make, have made, use, sell, offer for sale and import ***
(ii) Connetics, its Affiliates and sublicensees hereunder shall *** for indications (including, without limitation, the treatment of ***

Connetics’ and its Affiliates’ and sublicensees’ *** shall terminate with respect to ***

(iii) In the event that any Third Party Product Rights held by a third party *** revert to Genentech, then Genentech shall notify Connetics or its designated sublicensee in Japan of such reversion, and upon such notice Genentech shall be deemed to have automatically granted to Connetics the license under Genentech Patent Rights and under Genentech Knowhow to all such reverted rights, which license shall be exclusive to the extent that such reverted rights were exclusive. All rights granted to Connetics pursuant to this subsection (iii) shall be subject to the terms of this Agreement, including without limitation subsection (ii) above, Section 3.2(g) and Section 8.3.

(h) In the event that any Third Party Product Rights (other than those described in subsection (g) above) shall revert to Genentech, then Genentech shall notify Connetics of such reversion. For the ninety (90) day period following its receipt of such notice, Genentech and Connetics shall negotiate exclusively in good faith the reasonable commercial terms upon which Genentech would be willing to grant to Connetics the license to such reverted rights. If the Parties fail to enter a written agreement for a license to such rights by the end of such ninety (90) day period, then Genentech shall have no further obligation to Connetics with respect to such rights; provided that for six (6) months following such ninety *** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
(90) day period, Genentech shall not enter into an agreement to grant a license to such rights with a third party on terms that, taken as a whole, are less favorable to Genentech than those last offered by Connetics for such rights. ***

Nothing in the preceding sentence shall imply any *** Connetics may not transfer its rights under this Section 2.1(h) to any party other than InterMune without Genentech’s prior written consent.

Except as expressly granted herein, there are no implied licenses under the Genentech Patent Rights or any other intellectual property rights owned or controlled by Genentech.

12. Section 2.3(b) of the License Agreement is hereby deleted and replaced in its entirety as follows:

(b) Connetics may grant one or more sublicenses under the rights granted in Sections 2.1(a), (b), (c), (e), (f) and (g) in the Field of Use and the Gene Therapy Field of Use, on thirty (30) days prior written notice to Genentech, and subject to Genentech’s prior written approval, which approval shall not be unreasonably withheld.

13. A new Section 3.2(g) is hereby added to read in its entirety as follows:

(g) In addition to the Clinical Development Milestones (as set forth in Exhibit E hereto), Connetics shall use its Best Efforts to develop and commercialize Licensed Products: (i) in the Field of Use with respect to indications and diseases that, under the provisions of this Amendment, have been added to the “Field of Use” as defined in the original License Agreement executed as of May 5, 1998, and (ii) in the Gene Therapy Field of Use. Such additional indications and diseases in the Field of Use, and the Gene Therapy Field of Use, collectively are referred to in this subsection (g) as the “Additional Indications.” In the event that Connetics is not conducting such development efforts with respect to any Additional Indication(s) in a country or countries in the Territory as of the *** (or if rights to such Additional Indication were granted to Connetics pursuant to Section 2.1(g)(iii), then as of the *** that Genentech notifies Connetics or its designated sublicensee regarding such rights as set forth in that Section) or at any time thereafter, Genentech shall have the right to terminate this Agreement, and the licenses granted hereunder, with respect to Licensed Products for such Additional Indication(s) in such country or countries, upon *** days prior written notice to Connetics, unless Connetics can reasonably ***

Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.

7
14. Sections 8.2(a) and (b) of the License Agreement are hereby deleted and replaced in their entirety as follows:

(a) within thirty (30) days following the dates on which the first NDA or BLA, as applicable, for a Licensed Protein Product is filed with the FDA by Connetics for***; provided however, that such milestone payments shall only be paid once for each of the foregoing indications, and shall not be paid upon the filing of a NDA or BLA for an osteopetrosis or any mycobacterial infection indication.

(b) within thirty (30) days following the date Connetics receives the first FDA approval of ***; provided however, that such milestone payment shall only be paid once for each of the foregoing indications, and shall not be paid upon receipt of FDA approval for commercial sale for an osteopetrosis or any mycobacterial infection indication.

15. Section 8.3 of the License Agreement is hereby deleted and replaced in its entirety as follows:

8.3 Royalties. Connetics shall pay Genentech the following royalties on Net Sales of Licensed Products by Connetics and its sublicensees:

(a) For annual aggregate Net Sales of all Licensed Protein Products in the Territory (excluding Japan) ***, a royalty rate equal to *** of such Net Sales.

(b) For annual aggregate Net Sales of all Licensed Protein Products in the Territory (excluding Japan) ***, a royalty rate equal to *** of such Net Sales.

(c) For Net Sales of all Licensed Protein Products in Japan, a royalty rate equal to *** of such Net Sales; provided, however, that in the event that *** for an indication for which InterMune has exclusive rights under Section 2.1(g), the foregoing royalty rate shall be reduced to *** for Net Sales of *** in Japan for such indication ***

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
(d) (i) For Net Sales of Licensed Gene Product in the Territory, where such Licensed Gene Product is used in conjunction with a Licensed Protein Product for the treatment or prevention of a given indication in a given patient population, a royalty rate equal to *** of such Net Sales. As used in this subsection (d), “indication” shall mean any particular medical condition within the Field of Use and Gene Therapy Field of Use, including but not limited to labeling claims approved by a regulatory agency.

(ii) For Net Sales of Licensed Gene Product in a country in the Territory, where such Licensed Gene Product is used in a given patient population for the treatment or prevention of the same indication for which a given Licensed Protein Product is used in such patient population, a royalty rate equal to (A) *** of such Net Sales during the *** period following the first commercial sale of such Licensed Gene Product in such country for the treatment or prevention of such indication in such patient population by Connetics, or its Affiliates and sublicensees (the “First Commercial Sale”); (B) *** of such Net Sales during the *** period following the First Commercial Sale; and (C) *** of such Net Sales beginning on the *** anniversary of the First Commercial Sale and thereafter.

(iii) Notwithstanding the provisions of subsections (i) and (ii) above, in the event that annual Net Sales of a Licensed Gene Product for the treatment or prevention of such indication in such patient population in such country *** for the treatment or prevention of such indication in such patient population in such country, the royalty rate thereafter applicable to Net Sales of such Licensed Gene Product for the treatment or prevention of such indication in such patient population in such country shall be ten percent (10%) of such Net Sales.

(iv) In the event that Connetics or InterMune determines at any point following *** that the above royalty rates are having or are likely to have an adverse impact on Connetics’ or InterMune’s ability to compete effectively in its sales of such Licensed Gene Product, Connetics or InterMune shall so notify Genentech, and the Parties shall in good faith discuss and attempt to reach a reasonable and mutually agreeable resolution to the situation.

(e) (i) The royalties set forth in subsections (a), (b) and (c) above shall be payable, on a country-by-country basis, until the later of: (A) the expiration or revocation of the last remaining issued patent in such country within the Genentech Patent Rights that covers Licensed Protein Products, or (B) *** years from the Effective Date of this Agreement. Notwithstanding the **
foregoing, upon the expiration of the last to expire issued patent in each country within the Genentech Patent Rights during the term of this Agreement, thereafter each of the royalty rates set forth in (a), (b) and (c) above shall be reduced by *** with respect to such country.

(ii) The royalties set forth in subsection (d) above shall be payable, on a country-by-country basis, until the expiration or revocation of the last remaining issued patent in such country within the Genentech Patent Rights that covers Licensed Gene Products.

16. Section 8.4 of the License Agreement is hereby deleted and replaced in its entirety as follows:

8.4 Third-Party Royalties. If Genentech or Connetics is required to pay any third party a royalty due to the manufacture, use, sale, offer for sale or importation of a Licensed Product in the Territory for or by Connetics or its sublicensees, Connetics shall be responsible for the payment of *** of such third-party royalty, provided however, that Connetics may deduct from the royalties otherwise payable to Genentech under Section 8.3 above, an amount equal to *** of such third party royalties incurred only due to use patents in the Field of Use or in the Gene Therapy Field of Use in the Territory, provided that the amount deducted shall not exceed *** of the royalties otherwise payable by Connetics to Genentech under Section 8.3. For purposes of clarification, such deductions shall not apply to ***. Attached hereto as Exhibit G is a list of all such royalty obligations to third parties known to Genentech as of the Effective Date without diligent search. No later than thirty (30) days from the Effective Date, Genentech shall complete a reasonable internal investigation of its records and update Exhibit G, as necessary, to accurately reflect all such royalty obligations to third parties to the best of Genentech’s knowledge; provided however, Connetics acknowledges that Genentech has no obligation to conduct due diligence or any investigation with respect to third party patent rights related to Licensed Products. Genentech shall notify Connetics in writing during the term of this Agreement if it becomes aware of any additional Genentech third party royalty obligations.

17. Section 8.5 of the License Agreement is hereby deleted and replaced in its entirety as follows:

8.5 Royalty Payments.

(a) Royalty payments shall be made to Genentech quarterly within ninety (90) days following the end of each calendar quarter for which royalties are due. Each royalty payment shall be accompanied by a report summarizing the total Net Sales during the relevant three-month period, and the calculation of royalties, if any, due thereon pursuant to Section 8.3.

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
(b) Notwithstanding subsection (a) above, any royalty payments which accrue during 1999 on Net Sales of Licensed Protein Product sold by Connetics’ sublicensee InterMune shall be paid to Genentech in the form of promissory note, in the form attached hereto as Exhibit I. For each calendar quarter in 1999 for which royalty payments are due, InterMune shall execute and deliver to Genentech, within ninety (90) days following the end of each such calendar quarter, a promissory note in the form of Exhibit I, and in the amount of such royalties due to Genentech for such quarter. Each such promissory note shall be accompanied by the report described in Section 8.5(a) above for such quarter. In the event that any such note is delivered by InterMune after such 90 day period, nevertheless interest shall accrue on the date that such note was due.

18. The following provision is hereby inserted as Section 10.4 to the License Agreement:

10.4 Insurance. At all times during the term of this Agreement, Connetics and its sublicensees shall provide the following insurance at its sole cost and expense:

(a) Commercial General Liability, including coverage for products and completed operations (maintained for a period of at least *** after the expiration or termination of this Agreement) ***. The policy shall have a limit of no less than *** dollars.

(b) Foreign Local Coverages: Where required by law, Connetics and its sublicensees will purchase foreign local coverages in an amount that, at a minimum, satisfies the legal requirements of that jurisdiction.

(c) Policy Conditions: All policies under (a) and (b) above shall:

(i) be written by insurance companies with an A.M. Best’s rating of A:VIII or higher (or if Connetics’ or its sublicensees policies are not subject to the Best rating, then by carriers who are acceptable to Genentech); and

(ii) add Genentech as an additional insured.

(d) Additionally, Connetics shall use its Best Efforts to obtain from its insurance carrier for the policies described in subsections (a) and (b) covenants:

(i) ***

(ii) ***

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
Section 11.1 of the License Agreement is hereby deleted and replaced in its entirety as follows:

11.1 Term. This Agreement shall commence on the Effective Date of this Agreement and, unless terminated earlier, shall expire:

(a) With respect to Licensed Protein Products, at the later to occur of (i) the expiration of the last to expire of any Genentech Patent Rights covering a Licensed Protein Product, or (ii) twenty (20) years from the Effective Date of this Agreement; and

(b) With respect to Licensed Gene Products, at the expiration of the last to expire of any Genentech Patent Rights covering a Licensed Gene Product;

provided, however, that in the event that either the CMCC License or the Biogen License is terminated, the licenses granted by Genentech to Connetics under the CMCC License or the Biogen License shall also terminate. Genentech shall use its Best Efforts to keep the CMCC License and the Biogen License in effect during the term of this Agreement, ***

One year before the expiration of this Agreement under Section 11.1(a), the Parties agree to meet and to discuss in good faith extending the term of this Agreement with respect to Licensed Protein Products on terms mutually agreeable to the Parties.

Exhibit E of the License Agreement is hereby deleted and replaced in its entirety with new Exhibit E attached hereto and incorporated herein.

In consideration for the rights granted to Connetics and its sublicensees under this Amendment, ***

This Amendment supersedes the Letter Agreement in its entirety. All other terms and provisions of the License Agreement, including all exhibits to that Agreement, will continue in full force and effect as though fully set forth in this Amendment. Nothing in this Amendment shall be construed as affecting Connetics’ obligations to be liable and responsible for the performance of all of the obligations of Connetics and its sublicensees under the License Agreement.

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*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by the respective duly authorized officers as of the date first written above.

GENENTECH, INC.

By: /s/ Nicholas J. Simon
Printed Name: Nicholas J. Simon
Title: Vice President, Business and Corporate Development

CONNETICS CORPORATION

By: /s/ Thomas G. Wiggans
Printed Name: Thomas G. Wiggans
Title: President and Chief Executive Officer

Acknowledged and agreed as to InterMune’s rights and obligations hereunder as Connetics’ sublicensee under the License Agreement:

INTERMUNE PHARMACEUTICALS, INC.

By: /s/ Scott Harkonen
Printed Name: Scott Harkonen, M.D.
Title: President
Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
CONSENT TO ASSIGNMENT AGREEMENT

BETWEEN

CONNETICS AND

INTERMUNE PHARMACEUTICALS, INC.

JUNE 23, 2000

THIS CONSENT TO ASSIGNMENT AGREEMENT (this “Agreement”) is made effective and entered into as of June 23, 2000 (the “Effective Date”) by and between GENENTECH, INC., a Delaware corporation, with a principal place of business at 1 DNA Way, South San Francisco, California 94080 (“Genentech”), CONNETICS CORPORATION, a Delaware corporation, with a principal place of business at 3400 Bayshore Road, Palo Alto, California 94303 (“Connetics”) and INTERMUNE PHARMACEUTICALS, INC., a Delaware corporation, with a principal place of business at 1710 Gilbreth Road, Suite 301, Burlingame, CA 94010 (“InterMune”). Genentech, Connetics and InterMune may be referred to herein as a “Party” or collectively as the “Parties.”

RECITALS

A. WHEREAS, InterMune is a corporation formed for the purpose of research and development of biopharmaceutical products for the treatment of infectious and autoimmune diseases;

B. WHEREAS, Connetics has licensed the rights to certain immunology-based products and to the technology relating thereto from Genentech pursuant to that certain License Agreement for Interferon Gamma by and between Connetics and Genentech, dated May 5, 1998, as amended (the “Genentech License”);

C. WHEREAS, InterMune and Connetics have entered into that certain Amended and Restated Exclusive Sublicense Agreement, dated April 27, 1999 (the “Original Agreement”), pursuant to which (a) Connetics granted an exclusive sublicense to InterMune under the Genentech License to develop, make, have made, import, offer for sale and sell therapeutic products containing or derived from such immunology-based products and technology for use for certain specific indications, and (b) InterMune granted to Connetics the exclusive option to practice such sublicensed rights in the dermatology field;

D. WHEREAS, InterMune and Connetics now desire to supersede and replace the Original Agreement in order to assign to InterMune Connetics’ entire right, title and interest in, to and under the Genentech License by entering into that certain Assignment and Option Agreement, in the form attached hereto as Exhibit A (the “Assignment Agreement”); and

E. WHEREAS, pursuant to section 12.4 of the Genentech License, with the prior written consent of Genentech, Connetics may assign the Genentech License to InterMune.

NOW THEREFORE, in consideration of the above recitals and the covenants set forth herein, the parties hereto agree as follows:
1. Genentech consents to the assignment by Connetics to InterMune of all Connetics’ right, title and interest in and to the Genentech License.

2. On the Effective Date, Genentech unconditionally releases and discharges Connetics from any and all obligations under the Genentech License, and Genentech deems InterMune to be the successor in interest of Connetics under the Genentech License. Notwithstanding the above, Connetics shall remain responsible for all of its obligations, if any, under Section 8.1 of the Genentech License.

3. InterMune shall assume all of the obligations of and is entitled to all the rights of Connetics under the Genentech License, except that Connetics shall remain responsible for all of its obligations, if any, under Section 8.1 of the Genentech License.

4. Section 1.28 of the Genentech License is hereby amended in its entirety to read as follows:

   “1.28 “Territory” shall mean the United States of America and Canada, and their respective territories and possessions, and Japan.”

5. Nothing herein shall alter or affect the Stock Agreement or Stock Agreement Amendment (both defined in the Genentech License) between Connetics and Genentech.

6. This agreement may be executed in two or more counterparts, each of which shall be an original and all of which shall constitute together the same document.

7. This agreement shall be governed in accordance with the laws of the State of California, exclusive of its conflicts of laws provisions.

IN WITNESS WHEREOF, each of Genentech, Connetics and InterMune have executed this Agreement, as of the day and year first written above.

INTERMUNE PHARMACEUTICALS, INC.

By: /s/ W. Scott Harkonen
Print Name: W. Scott Harkonen
Title: Pres. & CEO

GENENTECH, INC.

By: /s/ Art Levinson
Print Name: Art Levinson
Title: CEO

CONNETICS CORPORATION

By: /s/ Thomas G. Wiggans
Print Name: Thomas G. Wiggans
Title: Pres. & CEO
January 25, 2001

Ms. Anna Hall
Director of Business Development
Genentech, Inc.
1 DNA Way
South San Francisco
CA 94080-4990

RE: AMENDMENT NO. 5 TO THE INTERMUNE/GENENTECH LICENSE AGREEMENT

Dear Ms. Hall:

Please consider this document as Amendment No. 5 to that certain License Agreement for Interferon Gamma, dated May 5, 1998; as amended on December 26, 1998; January 15, 1999; April 27, 1999; and June 23, 2000 (collectively, the “Agreement”), between INTERMUNE PHARMACEUTICALS, INC. and GENENTECH, INC. (collectively, the “Parties”).

1. The Parties agree that the first sentence of Section 2.2(b) of the Agreement is hereby terminated in its entirety and amended and superseded as follows:

“(b) Use of the Mark. In using the Actimmune mark, InterMune shall display said mark with either the first letter in uppercase (i.e., Actimmune) or all letters in uppercase (i.e., ACTIMMUNE).”

2. All other sections and exhibits of the Agreement remain unchanged.

3. This Amendment No. 5 to the Agreement is made effective as of January 25, 2001.

IN WITNESS THEREOF, the parties have executed this Amendment No. 5 to the Agreement as of the date set forth below.

INTERMUNE PHARMACEUTICALS, INC.

By /s/ John Wulf
John Wulf
Sr. Vice President of Corporate Development

Date January 25, 2001

GENENTECH, INC.

By /s/ Joseph S. McCracken
Joseph S. McCracken
VP Business Development

Date 4/5/01
AMENDMENT No. 6 to the License Agreement for Interferon Gamma

THIS AMENDMENT NUMBER SIX TO THE LICENSE AGREEMENT FOR INTERFERON GAMMA ("Amendment") is entered into effective February, 2006 (the “Amendment Effective Date”), by and between Genentech, Inc. (“Genentech”) and InterMune, Inc. (“InterMune”). Genentech and InterMune may each be referred to herein as a “Party” and jointly as the “Parties.”

RECITALS

WHEREAS, Genentech and InterMune are each parties to that certain License Agreement for Interferon Gamma executed on May 5, 1998, as amended to date (the “Agreement”); and

WHEREAS, Genentech and InterMune desire to further amend the Agreement as specified herein below.

NOW, THEREFORE, in consideration of the mutual covenants and conditions hereinafter set forth, and intending to be legally bound, Genentech and InterMune hereby agree as follows:

Except as modified and/or amended herein, all of the terms, covenants and conditions contained in the Agreement shall remain unchanged and in full force and effect. The term “Agreement”, as used in the Agreement, and all other instruments and agreements executed thereunder, shall for all purposes refer to the Agreement as amended by this Amendment. This Amendment may be executed in counterpart, each of which shall be deemed to be an original, and such counterparts together shall constitute one instrument. In the event of a conflict among the terms and conditions of this Amendment, and the Agreement, the following order of precedence shall prevail:

a. this Amendment; and
b. the Agreement.

CHANGES TO THE AGREEMENT. THE FOLLOWING CHANGES ARE HEREBY MADE TO THE AGREEMENT:

(a) Section 3.2, Section 3.2 is hereby deleted in its entirety and replaced with the following new Section 3.2:

“3.2 Diligence. InterMune shall use its Best Efforts to develop and commercialize Licensed Products in the Field of Use and in the Gene Therapy Field of Use, in accordance with the development plan roadmap set forth on Exhibit E hereto (the “Development Plan Roadmap”).”
(b) Section 3.3. Section 3.3 is hereby deleted in its entirety and replaced with the following new Section 3.3:

“3.3 Review of Clinical Development Plan and Marketing Programs. On or about each August 1 during the term of this Agreement, InterMune shall supply Genentech with a report on InterMune’s development and marketing programs for Licensed Products in the Field of Use and the Gene Therapy Field of Use in the Territory. The report shall include the following: (i) a description of InterMune’s progress in such programs during the twelve (12) months prior to the date of each such report, and (ii) a description of InterMune’s planned development and marketing programs for the twelve (12) months after the date of each such report. Genentech shall have the right to comment on the development and marketing programs, and at Genentech’s discretion, the Parties shall meet to discuss and agree upon changes to such development and marketing programs.”

(c) Section 3.8. Section 3.8 is hereby deleted in its entirety and replaced with the following new Section 3.8:

“3.8 Clinical Development Reports. In connection with InterMune’s reporting obligations set forth in Section 3.3 hereof with respect to the development of Licensed Products and clinical studies conducted by InterMune hereunder, InterMune shall provide to Genentech any information/report set forth in Exhibit F hereto as may be requested by Genentech in writing. InterMune shall submit such information/report to Genentech as promptly as reasonably practicable after such reports are completed or such applicable information is available.”

(d) Exhibit E. Exhibit E is hereby deleted in its entirety and replaced with the new Exhibit E attached hereto.

(e) In Witness Whereof, the Parties have caused this Amendment to be executed by the respective duly authorized officers as of the date first written above.

GENENTECH, INC.

By: /s/ Joseph S. McCracken
Printed Name: Joseph S. McCracken
Title: VP Business Development

INTERMUNE, INC.

By: /s/ Tom Kassberg
Printed Name: Tom Kassberg
Title: Sr. VP Corporate Development
Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.
SEVENTH AMENDMENT
TO
LICENSE AGREEMENT FOR INTERFERON GAMMA

This Seventh Amendment To License Agreement for Interferon Gamma (hereinafter “Seventh Amendment”) is entered into effective December 17, 2013 (the “Seventh Amendment Effective Date”) by and between Genentech, Inc. (“Genentech”) and Vidara Therapeutics International Limited, (“Vidara”), who are now Parties to the License Agreement for Interferon Gamma dated May 5, 1998, as amended. Genentech and Vidara may each be referred to herein as a “Party” and jointly as the “Parties.”

RECITALS

WHEREAS, on May 5, 1998, Genentech and Connetics Corporation (hereinafter “Connetics”) entered into the License Agreement for Interferon Gamma.

WHEREAS, the May 5, 1998 License Agreement for Interferon Gamma was amended by the following: (i) Amendment No. One, dated December 28, 1998; (ii) Amendment No. Two, dated January 15, 1999; (iii) Amendment No. Three, dated April 27, 1999; (iv) Consent To Assignment Agreement, dated June 23, 2000; (v) Amendment No. 5, dated January 25, 2001; (vi) Amendment No. 6, dated February 27, 2006; (vii) Fee Agreement Letter dated June 23, 2011; (viii) Consent to Assignment dated June 23, 2011, (hereinafter collectively “Agreement”), resulting in Genentech and Vidara being the Parties to the Agreement.

WHEREAS, Genentech and Vidara desire to further amend the Agreement as specified hereinbelow.

NOW THEREFORE, in consideration for the mutual covenants and conditions set forth below and other valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the Parties, the Parties make the following Seventh Amendment to the Agreement (hereinafter “Seventh Amendment”) and agree as follows:

I. GENERAL

1. Except as expressly defined herein, all capitalized terms shall have the meanings set forth in the Agreement.

2. Except as modified and/or amended herein, all of the terms, covenants and conditions contained in the Agreement shall remain unchanged and in full force and effect. In the event of a conflict among the terms and conditions of this Seventh Amendment, and the Agreement, this Seventh Amendment shall prevail.
II. AMENDMENTS TO AGREEMENT

2.0 License Grant

Section 2.2(a) of the Agreement is hereby deleted and replaced in its entirety with the following:

2.2 Trademark License Grant

(a) Genentech hereby grants to Vidara an exclusive license to use the trademark, ACTIMMUNE, for the advertising, promotion, marketing, distribution and sale of License Products in the Territory. Vidara shall have the right to grant sublicenses of such exclusive license, subject, however, to the prior written consent of Genentech, which consent shall not be unreasonably withheld or delayed.

5.0 Intellectual Property Rights

A new Section 5.7 is hereby added to the Agreement to read in its entirety as follows:

5.7 Trademark Maintenance. Genentech shall protect and maintain the ACTIMMUNE trademark in the Territory, including, without limitation, renewing and maintaining in full force U.S. Trademark Registration No. 1,617,288 for the word mark ACTIMMUNE (hereinafter “U.S. Trademark Registration”), as well as Canadian Registration No. (373897) and Japanese Registration No. [to be filed upon written request by Vidara] (collectively “Trademark Registrations”).

Genentech shall be responsible for renewing and maintaining the U.S. Trademark Registration, and any other trademark registration for the ACTIMMUNE mark in the Territory, in good standing, including the timely payment of all renewal fees, maintenance fees, government fees or the like, necessary to so maintain the Trademark Registrations and any foreign counterparts. Genentech shall defend against any cancellation, challenge or like proceeding brought in the U.S. Patent and Trademark Office, or any like office in the Territory, against the ACTIMMUNE mark and shall bear all such fees and costs, including attorney fees, associated therewith.

Genentech shall not assign the ACTIMMUNE mark or Trademark Registrations to any third party without the prior written consent of Vidara, and any such assignment shall be subject to this Agreement.

8.0 Up-Front Payment, Milestone Payments and Royalties

A new Section 8.3(f) is hereby added to the Agreement to read in its entirety as follows:

8.3(f) Notwithstanding anything herein to the contrary, effective May 5, 2018, and extending for the remainder of the Term of the Agreement, Vidara shall pay Genentech the following royalties on Net Sales of Licensed Products by Vidara and its sublicensees as sole compensation to Genentech for all trademark rights granted under this Agreement:

Execution Version
(i) For annual aggregate Net Sales of all Licensed Products in the Territory of up to and including ***$, a royalty rate of *** of such Net Sales;

(ii) For annual aggregate Net Sales of all Licensed Products in the Territory exceeding ***$, a royalty rate equal to *** of such Net Sales exceeding ***.

11.0 Term and Termination

Section 11.1 of the Agreement is hereby deleted and replaced in its entirety with the following:

11.1 Term. This Agreement shall commence on the Effective Date of this Agreement and, unless terminated earlier, shall expire:

(a) With respect to Licensed Protein Products, at the later to occur of (i) the expiration of the last to expire of any Genentech Patent Rights covering a Licensed Protein Product; (ii) twenty (20) years from the Effective Date of this Agreement; or (iii) upon Vidara or Vidara’s successors, licensees or assignees, permanently ceasing, without intending to resume, the sale of Licensed Product in every country that comprises the Territory; and

(b) With respect to Licensed Gene Products, at the expiration of the last to expire of any Genentech Patent Rights covering a Licensed Gene Product;

provided however, that in the event that either the CMCC License or the Biogen License is terminated, the licenses granted by Genentech to Connetics under the CMCC License or the Biogen License shall also terminate. Genentech shall use its Best Efforts to keep the CMCC License and the Biogen License in effect during the term of this Agreement, provided, however, that if Connetics declines to pay a CMCC benchmark payment as outlined in Section 5.2(c) or pay any royalty owed to CMCC under the CMCC License for the sales of Licensed Products, then Genentech shall not be obligated to make such payment and Genentech shall have the option, in its sole discretion, to terminate the CMCC Licensee.

Section 11.6 of the Agreement is hereby deleted in its entirety and replaced in its entirety with the following:

11.6 Unilateral Termination. Genentech shall not have the right to unilaterally terminate this Agreement, provided that Genentech may terminate this Agreement in accordance with Section 11.2 (Termination for Default). In addition to any other right of termination provided herein, Vidara shall have the right to terminate this Agreement for any reason, with or without cause, upon six (6) months prior written notice to Genentech. If Vidara terminates this Agreement pursuant to this Section 11.6, Vidara agrees that for the following three (3) years it will not use, sell or acquire from any third party (whether by license or otherwise) any Licensed Product in the Field of Use. If Vidara terminates this Agreement pursuant to this Section 11.6,

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.

Execution Version 3
III. MISCELLANEOUS

1. **Counterparts.** This Seventh Amendment may be executed in counterparts (including signatures by facsimile), each of which shall be deemed an original, but all of which together shall constitute but one and the same Seventh Amendment.

2. **Warranty of Authority.** Each signatory below warrants that he/she is the authorized agent of the respective Party he/she represents and that he/she has the authority to enter into the Seventh Amendment and to bind the Party thereto.

3. **Severability.** If any provision of this Seventh Amendment is held to be invalid by any court of competent jurisdiction, then the remaining provisions shall nevertheless remain in full force and effect. The parties agree to re-negotiate any term held invalid and to be bound by the mutually agreed upon substitute provision.

IN WITNESS WHEREOF; the parties hereto have caused this Seventh Amendment to the Agreement to be executed by two of their duly authorized representatives:

**GENENTECH, INC.**

By: /s/ Steve Krognes  
Name: Steve Krognes  
Title: Chief Financial Officer  
Dated: 12/18/13  

**VIDARA THERAPEUTICS INTERNATIONAL LTD.**

By: /s/ Samira Saya  
Name: Samira Saya  
Title: Director  
Dated: 17th December 2013
ASSIGNMENT AND OPTION AGREEMENT

BY AND BETWEEN

INTERMUNE PHARMACEUTICALS, INC.

AND

CONNETICS CORPORATION

JUNE 23, 2000

(SUPERSEDING AND REPLACING THE AMENDED AND RESTATED EXCLUSIVE SUBLICENSE AGREEMENT OF APRIL 27, 1999)
ASSIGNMENT AND OPTION AGREEMENT

THIS ASSIGNMENT AND OPTION AGREEMENT (the “Agreement”) is made effective and entered into as of June 23, 2000 (the “Effective Date”) by and between CONNETICS CORPORATION, a Delaware corporation, with a principal place of business at 3400 West Bayshore Road, Palo Alto, CA 94303 (“Connetics”), and INTERMUNE PHARMACEUTICALS, INC., a Delaware corporation, with a principal place of business at 1710 Gilbreth Road, Suite 301, Burlingame, CA 94010 (“InterMune”). Connetics and InterMune may be referred to herein as a “Party” or collectively as the “Parties.”

RECITALS

A. WHEREAS, InterMune is a corporation formed for the purpose of research and development of biopharmaceutical products for the treatment of infectious and autoimmune diseases; and

B. WHEREAS, Connetics has licensed the rights to certain immunology-based products and to the technology relating thereto from Genentech, Inc. (“Genentech”) pursuant to that certain License Agreement for Interferon Gamma by and between Connetics and Genentech, dated May 5, 1998, as amended (the “Genentech License”); and

C. WHEREAS, InterMune and Connetics have entered into that certain Amended and Restated Exclusive Sublicense Agreement, dated April 27, 1999 (the “Original Agreement”), pursuant to which (a) Connetics granted an exclusive sublicense to InterMune under the Genentech License to develop, make, have made, import, offer for sale and sell therapeutic products containing or derived from such immunology-based products and technology for use for certain specific indications, and (b) InterMune granted to Connetics the exclusive option to practice such sublicensed rights in the dermatology field; and

D. WHEREAS, InterMune and Connetics now desire to supersede and replace the Original Agreement as further set forth herein in order to assign to InterMune Connetics’ entire right, title and interest in, to and under the Genentech License.

NOW, THEREFORE, the Parties agree as follows:

1. DEFINITIONS

1.1 “Affiliate” means any company or entity controlled by, controlling or under common control with a Party. As used in this Section, “control” means (a) that an entity or company owns, directly or indirectly, fifty percent (50%) or more of the voting stock of another entity, or (b) that an entity, person or group has the actual ability to control and direct the management of the entity, whether by contract or otherwise, but excluding, for all purposes of this Agreement, Connetics, as to InterMune, and InterMune, as to Connetics.

1.2 “Amendment No. 3” means that certain Amendment No. Three to License Agreement entered into between Connetics and Genentech, effective April 27, 1999. For clarity, the phrase “as amended by Amendment No. 3” as used herein is intended only for ease of reference and not as a limitation.
1.3 “Best Efforts” means every necessary and prudent effort of a Party applied in a prompt, commercially reasonable manner, to the maximum extent reasonably allowed by such Party’s available financial resources, taking into account all of such Party’s business commitments for such financial resources.

1.4 “BLA” means a Biologics License Application.

1.5 “Connetics Know-How” means all Know-How in the areas of quality assurance/quality control (QA/QC), pharmaceutical science, process development or regulatory affairs that (a) is Controlled by Connetics during the term of this Agreement, and (b) is necessary or useful to the discovery, development, use or manufacture of Products, but excluding all Know-How that is part of the Genentech License Rights.

1.6 “Controlled” means with respect to any material, Know-How or intellectual property right, that the Party owns or has a license to such material, Know-How or intellectual property right and has the ability to grant access, a license, or a sublicense to such material, Know-How or intellectual property right to the other Party as provided for herein without violating an agreement with a Third Party as of the time the Party would be first required hereunder to grant the other Party such access, license or sublicense.

1.7 “Dermatology Field” means the administration to humans of therapeutic products for the treatment, prevention or diagnosis of any dermatological disease or condition, including, without limitation, atopic dermatitis, keloids/hypertrophic scars, pustular psoriasis and scleroderma, but excluding (a) any cancer disease or condition, (b) any infectious disease or condition, and (c) any indication outside of the IG Field.

1.8 “Dermatology Sublicensee” means a Third Party to which Connetics has granted a sublicense under the sublicense rights to be granted by InterMune to Connetics following Connetics’ exercise of its option pursuant to Section 4.1.

1.9 “FDA” means the U.S. Food and Drug Administration, or any successor agency.

1.10 “Gene Therapy” means the therapeutic or prophylactic treatment of a human being with: (a) one or more oligonucleotides or nucleotide sequences, in native form or chemically modified, which are introduced into the body in free form, bound to a carrier molecule, contained in any molecular vesicle (e.g. a liposome), incorporated into or attached to a vector of any type, contained in any cellular construct and/or contained in any mechanical device or (b) cells which have been manipulated ex vivo using one or more oligonucleotides or nucleotide sequences.

1.11 “Gene Therapy Field” means the administration to humans of Licensed Gene Product for Gene Therapy for the treatment or prevention of any human disease or condition, provided however, that “Gene Therapy Field” shall not include any treatment or prevention of any type of cardiac or cardiovascular disease or condition.

1.12 “Genentech” means Genentech, Inc., a Delaware corporation, with its principal office at 1 DNA Way, South San Francisco, CA 94080.
1.13 “Genentech License” means the License Agreement for Interferon Gamma between Genentech and Connetics, dated May 4, 1998; as amended by: Amendment No. 1 to License Agreement, effective December 28, 1998; Amendment No. 2 to License Agreement, effective January 15, 1999; Amendment No. 3; and that certain Consent to Assignment Agreement, dated as of the date hereof.

1.14 “Genentech License Rights” means all rights under Patents, Know-How and trademarks granted to Connetics by Genentech under the Genentech License, but only to the extent the Genentech License permits the practice of such rights for the uses set forth in Article 3 herein. “Genentech License Rights” shall not include any Third Party Product Rights.

1.15 “Genentech Patents” means all the Patent rights which are granted to Connetics under the Genentech License.


1.17 “IG Field” means the administration to humans of Licensed Protein Product for the treatment or prevention of any human disease or condition, provided however, that “IG Field” shall not include: (a) the administration to humans of Licensed Protein Product for the treatment or prevention of any type of arthritis or cardiac or cardiovascular disease or condition or (b) use of Licensed Protein Product for Gene Therapy.

1.18 “Interferon Gamma” or “IG” means the polypeptide described as “Interferon Gamma” in Section 1.20 of the Genentech License.

1.19 “InterMune Net Sales” means “Net Sales” of Licensed Protein Products in the Territory for use in the IG Field by InterMune and its sublicensees hereunder other than Connetics and its Affiliates and Dermatology Sublicensees.

1.20 “Know-How” means all information, data, know-how, trade secrets, inventions, developments, results, techniques and materials, whether or not patentable.

1.21 “Licensed Product,” “Licensed Gene Product” and “Licensed Protein Product” shall each have the same meaning as defined in Section 1.22 of the Genentech License.

1.22 “Licensed Technology” means the Genentech License Rights and the Connetics Know-How.

1.23 “Net Sales” means “Net Sales” (as defined in Section 1.25 of the Genentech License) of Licensed Protein Products in the Territory for use in the IG Field by InterMune and any of its sublicensees hereunder (including without limitation Connetics, its Affiliates and its Dermatology Sublicensees).

1.24 “Original Agreement Effective Date” means April 27, 1999.
1.25 “Patents” means any and all issued or pending patents and patent applications, both foreign and domestic, and including without limitation (a) all divisionals, continuations and continuations-in-part of any such applications, (b) any patents that issue from any of the foregoing, and (c) all substitutions, extensions, reissues, renewals, supplementary protection certificates and inventors’ certificates with respect to any of the foregoing issued patents.

1.26 “Territory” shall have the meaning set forth in Section 1.28 of the Genentech License.

1.27 “Third Party” means any party besides the Parties and their respective Affiliates.

1.28 “Third Party Product Rights” shall have the meaning set forth in Section 1.37 of the Genentech License.

1.29 United States” means the United States and its territories and possessions.

2. ORIGINAL AGREEMENT SUPERSEDED

The Parties agree that the Original Agreement is hereby replaced and superseded in all respects by this Agreement as of the Effective Date, except as expressly set forth in Section 3.3.

3. ASSIGNMENT OF RIGHTS; LICENSE GRANT; RELATED COVENANTS

3.1 Assignment of Rights. Connetics agrees to assign and hereby does assign to InterMune Connetics’ entire right, title and interest in, to and under the Genentech License. Upon each request by InterMune, without additional consideration, Connetics agrees to promptly execute all documents and take all such acts as InterMune deems necessary or desirable to procure, maintain, perfect, and enforce the full benefits, enjoyment, rights, title and interest in, to and under the Genentech License assigned hereunder. In the event InterMune is unable for any reason, after reasonable effort, to secure Connetics’ signature on any document needed in connection with the actions specified herein, Connetics hereby irrevocably designates and appoints InterMune and its duly authorized officers and agents as its agent and attorney in fact, which appointment is coupled with an interest, to act for and on its behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of this Section 3.1 with the same legal force and effect as if executed by Connetics. Connetics agrees that as of the Effective Date, InterMune shall be deemed a party to and sole licensee under the Genentech License, and that Connetics shall have no further rights nor obligations hereunder, except as set forth in Section 4.1 of this Agreement and those obligations that accrued prior to the Effective Date, including without limitation, Connetics’ remaining obligations, if any, under Section 8.1 of the Genentech License. Connetics hereby covenants that it shall take no action inconsistent with InterMune’s rights as party to and licensee under the Genentech License.

3.2 Connetics Know-How. Connetics hereby grants to InterMune a non-exclusive license under the Connetics Know-How to develop, use, make, have made, import, offer for sale and sell (a) Licensed Products in the Territory, and (b) any products covered by Third Party Product Rights to which Connetics or InterMune acquires rights under the Genentech License in the applicable territory.
3.3 Genentech Supply Agreement. Pursuant to the Original Agreement, Connetics assigned to InterMune Connetics’ entire right, title and interest to the Genentech Supply Agreement, which assignment shall remain in full force and effect. InterMune hereby covenants that it shall maintain the Genentech Supply Agreement effective and in good standing. To the extent Connetics exercises its option pursuant to Section 4.1 below, InterMune shall procure for and supply to Connetics (and its Dermatology Sublicensees, if any) its requirements for Bulk Product and Finished Product (as such terms are defined in the Genentech Supply Agreement) for use in the Dermatology Field from Genentech pursuant to the Genentech Supply Agreement or from any Third Party manufacturer(s) contracted by InterMune to manufacture Finished Product and Bulk Product, provided that Connetics shall pay to InterMune InterMune’s cost, without markup, for procuring and supplying such Finished Product and Bulk Product to Connetics.

3.4 Transfer of Data and Materials. Promptly following the Effective Date, Connetics and InterMune shall work cooperatively together to transfer to InterMune all documents or materials in Connetics’ possession comprising or containing the Licensed Technology, including without limitation, biological and chemical materials, regulatory filings, and data, and Connetics shall transfer any and all additions or improvements to the Licensed Technology to InterMune as soon as is reasonably practicable after the creation, development or acquisition of such addition or improvements.

4. Option to Dermatology Rights

4.1 Option Grant. InterMune hereby grants to Connetics the exclusive option to obtain the exclusive sublicense under the Genentech License Rights to develop, use, make, have made, import, offer for sale and sell Licensed Protein Products for use solely in the Dermatology Field in the United States, subject to Genentech’s rights under the Genentech License. Connetics may exercise such option at any time prior to the fifth anniversary of the Original Agreement Effective Date by providing InterMune written notice of its desire to exercise such option. Upon InterMune’s receipt of such notice, InterMune shall be deemed to have granted to Connetics the exclusive, royalty-free (with respect to InterMune only), sublicense under the Genentech License Rights to use, make, have made, import, offer for sale and sell Licensed Protein Products in the Dermatology Field in the United States for the term of this Agreement, subject to the terms and conditions of the Genentech License relating to its development and commercialization of Licensed Protein Products in the Dermatology Field in the United States, including without limitation those obligations described in Sections 4.2 and 4.5 below. Such sublicense shall be further sublicenseable by Connetics to the extent permitted by the Genentech License. If not exercised by the fifth anniversary of the Original Agreement Effective Date, the option granted in this Section 4.1 shall expire.

4.2 Milestone Payments. If Connetics exercises its option under Section 4.1 then:

(a) In the event that Connetics or a Dermatology Sublicensee achieves one of the milestones set forth in Sections 8.2(a) or (b) of the Genentech License with respect to a Licensed Protein Product, Connetics or such Dermatology Sublicensee shall inform InterMune thereof and provide such milestone payment due under the Genentech License to InterMune.

5
In the event that milestone payments to Genentech as set forth in Sections 8.2(c) and (d) of the Genentech License are triggered by the sale of Licensed Protein Products by both Connetics and InterMune (and/or their sublicensees) in the Territory, the Parties shall promptly meet and in good faith determine a fair apportionment between the Parties of the payment to be made to Genentech for such milestone based upon the relative Net Sales of each Party for such calendar year or other agreed upon method of apportionment. Connetics shall then submit to InterMune its portion of such milestone payment in accordance with the terms of the Genentech License.

4.3 Royalties. If Connetics exercises its option under Section 4.1 then:

(a) Connetics shall pay royalties to InterMune on all Net Sales of Licensed Protein Products by Connetics, its Affiliates and its Dermatology Sublicensees at the applicable royalty rate set forth in Section 8.3 of the Genentech License (as may be reduced pursuant to Section 8.4 of the Genentech License).

(b) Royalty payments shall be made to InterMune quarterly within sixty (60) days following the end of each calendar quarter for which royalties are due. Each royalty payment shall be accompanied by a report summarizing the total Net Sales by Connetics, its Affiliates and its Dermatology Sublicensees during the relevant three-month period, and the calculation of royalties, if any, due thereon pursuant to subsection (a) above.

(c) Connetics, its Affiliates and its Dermatology Sublicensees hereunder shall keep full, true and accurate books of account containing all particulars which may be necessary for the purpose of showing Net Sales. Said books of account shall be kept at the principal place of business of Connetics, its Affiliates or its Dermatology Sublicensees, as the case may be. Said books and the supporting data shall be open at all reasonable times, for three (3) years following the end of the calendar year to which they pertain (and access shall not be denied thereafter, if reasonably available), to the inspection of an independent public accountant retained by InterMune or Genentech and reasonably acceptable to Connetics (or its Affiliate or Dermatology Sublicensee) for the purpose of verifying Net Sales under this Agreement; subject to the provisions of subsection (e) below.

(d) Connetics shall, within sixty (60) days after the end of each calendar quarter beginning with the quarter of the first commercial sale of a Licensed Protein Product in the Dermatology Field in the Territory by Connetics, its Affiliates or its Dermatology Sublicensees, deliver to InterMune a true and accurate report, setting forth such particulars of the business conducted by Connetics, its Affiliates and its Dermatology Sublicensees during the preceding quarter as are pertinent to an accounting for Net Sales and deductible expenses as permitted under the Genentech License. Such reports shall include at least the following: (i) the total gross sales of Licensed Protein Products occurring during that calendar quarter, (ii) the allowable deductions therefrom, (iii) the total Net Sales of Licensed Protein Products occurring during that calendar quarter and (iv) the calculation of royalties, if any, due thereon pursuant to subsection (a) above.

(e) At InterMune’s or Genentech’s request and expense, Connetics shall permit a certified public accountant selected by InterMune or Genentech and reasonably
acceptable to Connetics to examine, not more than once in any four consecutive calendar quarters during the term of this Agreement, but including one (1) post-termination audit, Connetics’ books of account and records of all sales of Licensed Protein Products by Connetics, its Affiliates and its Dermatology Sublicensees for the sole purpose of determining the correctness of the reports provided by Connetics under subsection (a) above. If such accountant reasonably determines that the royalties owed by Connetics to InterMune under subsection (a) above have been, for any calendar year in total, understated by Connetics, Connetics shall immediately pay to InterMune all understated royalties, together with interest on such royalties from the date accrued at a rate of prime plus 2% and shall pay the reasonable costs of the examination if Connetics has understated such royalties by more than 5%.

4.4 Off-Label Sales. If Connetics exercises the option set forth in Section 4.1 then:

(a) Each Party agrees and shall require its sublicensees, if any, to use commercially reasonable efforts to formulate all Licensed Protein Products developed by such Party or sublicensee thereof in a manner to reduce, to the extent reasonably practicable, the possibility that such Licensed Protein Product can be used in the other Party’s field of use as provided hereunder. If a Party cannot so formulate a particular Licensed Protein Product, then such Party agrees to use its Best Efforts to prevent sales of such Licensed Protein Product for use in the other Party’s field of use, including without limitation instructing its sales forces, and requiring all sublicensees to instruct their sales forces, that such Licensed Protein Product is not to be promoted, marketed or sold for use in the other Party’s field of use.

(b) In the event that either Party determines that a Licensed Protein Product sold by a Party or its sublicensees hereunder is being used in a field of use other than one for which such Party has the right to sell such Licensed Protein Product hereunder, the Party making such determination shall immediately inform the other Party. The Parties shall then promptly meet and diligently and in good faith determine a fair and reasonable mechanism for equitable allocation of the sales of such Licensed Protein Product that are used outside the field of use for which the selling Party had the right to sell.

4.5 Patent Costs. If Connetics exercises the option set forth in Section 4.1, then Connetics agrees to reimburse InterMune all costs paid by InterMune to Genentech under Section 5.2 of the Genentech License which relate to any patent or patent application the claims of which: (a) are specifically directed to a Licensed Protein Product for use in the Dermatology Field and (b) do not relate to a Licensed Protein Product for use in any area of the IG Field other than the Dermatology Field.

4.6 Milestone Payments. If Connetics exercises its option under Section 4.1, then Connetics shall make the following cash milestone payments to InterMune:

(a) One million two hundred thousand dollars ($1,200,000) within thirty (30) days following the date on which the first NDA or BLA for a Licensed Protein Product is filed with the FDA by Connetics, its Affiliate or its Dermatology Sublicensee for an indication in the Dermatology Field; and
(b) Two million dollars ($2,000,000) within thirty (30) days following the date Connetics, its Affiliate or its Dermatology Sublicensee receives FDA clearance for each new indication in the Dermatology Field of a Licensed Protein Product for commercial sale in the United States.

4.7 Dermatological Indications Outside of the Dermatology Field.

(a) It is the intention of the Parties that Connetics shall be InterMune’s preferred marketing partner for sales of Licensed Protein Product to dermatologists in the United States during the term of this Agreement. Therefore, during the term of this Agreement, if either Party desires to sell Licensed Protein Product to dermatologists in the United States for use for indications that are outside of the Dermatology Field but within the IG Field (an “Outside Indication”), the provisions of this Section 4.7 shall apply.

(b) In the event that either Party desires to sell a Licensed Protein Product for an Outside Indication to dermatologists in the United States during the term of this Agreement, such Party shall give the other Party written notice of such interest, which notice shall specify the indication of interest. If InterMune notifies Connetics that InterMune itself desires to sell such Licensed Protein Product for an Outside Indication directly to dermatologists in the United States, then the procedures of subsection (d) shall apply. Otherwise, for ninety (90) days following receipt of such notice, the Parties shall exclusively negotiate in good faith for the reasonable commercial terms under which Connetics shall exclusively sell such Licensed Protein Product for such Outside Indication to dermatologists in the United States. In the event that, at the end of such ninety (90) day period, the Parties have failed to enter into a written agreement on such commercially reasonable terms, Connetics’ rights with respect to the sale of such Licensed Protein Product for such Outside Indication shall terminate and InterMune shall have no further obligations to Connetics under this Section 4.7 with respect to such Licensed Protein Product for such Outside Indication except as set forth in subsections (c) and (d) below.

(c) If the Parties have failed to enter into an agreement by the end of such ninety (90) day period, as described in subsection (b) above, InterMune shall then have the right during the following one hundred eighty (180) day period to enter into an agreement with a Third Party for the sale to dermatologists of such Licensed Protein Product for such Outside Indication on economic terms that, taken as a whole, are substantially the same as, or more favorable to InterMune than, those last offered in writing by Connetics for such rights pursuant to subsection (b) above. If at the end of such one hundred eighty (180) day period InterMune has not entered into an agreement with a Third Party to sell such Licensed Protein Product for such Outside Indication to dermatologists in the United States, then the procedures set forth in subsection (b) above shall again apply, provided that InterMune may proceed alternatively under subsection (d) below.

(d) If InterMune itself desires to sell such Licensed Protein Product to dermatologists in the United States for Outside Indications, then upon written notice from InterMune, Connetics and InterMune shall enter into good faith negotiations, for a period of ninety (90) days from Connetics’ receipt of such notice, for the reasonable commercial terms upon which InterMune shall grant to Connetics the rights to co-promote such Licensed Protein Product for such Outside Indication to dermatologists in the United States. InterMune agrees
that it shall not unreasonably withhold its agreement to such commercially reasonable terms. In the event that, at the end of such ninety (90) day period, the Parties have failed to enter into a written agreement for such co-promotion rights, InterMune shall have no further obligations to Connetics under this Section 4.7 with respect to such Licensed Protein Product for such Outside Indication, provided that InterMune may not enter into an agreement with a Third Party for the rights to co-promote Licensed Protein Product for such Outside Indication to dermatologists in the United States on economic terms that, taken as a whole, are less favorable to InterMune than those last offered in writing by Connetics for such rights. In the event that InterMune does not enter into such a co-promotion agreement with a Third Party and instead solely promotes and sells such Licensed Protein Product for such Outside Indication to dermatologists in the United States itself, if at any time following such sole promotion and sale InterMune determines in its sole discretion that it desires to grant a license to the rights to promote and sell, or to co-promote, such Licensed Protein Product for such Outside Indication to dermatologists in the United States to a Third Party, then the procedures set forth in subsection (b) above shall apply.

5. CONSIDERATION

5.1 Royalties.

(a) Beginning on January 1, 2002, InterMune shall pay to Connetics a royalty of one-quarter of one percent (0.25%) of InterMune Net Sales in the United States. InterMune shall continue to pay such royalties to Connetics until such time as the cumulative InterMune Net Sales in United States, beginning on January 1, 2000, are equal to one billion dollars ($1,000,000,000). Thereafter, InterMune shall pay to Connetics a royalty of one-half of one percent (0.5%) of InterMune Net Sales in the United States for the remainder of the term of the Agreement.

(b) All royalties due under this Section 5.1 shall be due and payable quarterly within thirty (30) days following the last day of each quarter in which royalties are incurred beginning with first calendar quarter of 2002.

5.2 Milestone Payment. InterMune shall pay to Connetics a milestone payment of one million five hundred thousand dollars ($1,500,000), (the “Milestone Payment”), payable in a lump sum or in installments based on the level of InterMune Net Sales, as follows:

(a) If annualized InterMune Net Sales in the United States for 2001, based on InterMune Net Sales in the United States for the third and fourth calendar quarters of 2001, (“2001 Net Sales”) are equal to or greater than twenty million dollars ($20,000,000), then on March 31, 2002, InterMune shall, at its election, either (i) pay the full Milestone Payment to Connetics, or (ii) pay to Connetics three hundred seventy five thousand dollars ($375,000) of the Milestone Payment and furnish to Connetics a promissory note for the balance of the Milestone Payment, which promissory note shall provide for three (3) principal payments to Connetics of three hundred seventy five thousand dollars ($375,000) each due upon June 30, 2002, September 30, 2002 and December 31, 2002, respectively.

(b) If 2001 Net Sales are equal to or greater than fifteen million dollars ($15,000,000) but less than twenty million dollars ($20,000,000), then on March 31, 2002,
InterMune shall pay to Connetics three hundred thousand dollars ($300,000) of the Milestone Payment, and furnish to Connetics a promissory note for the balance of the Milestone Payment (the “Remaining Payment”), which promissory note shall provide for full payment of the balance of such note to Connetics on the earlier to occur of (i) March 31, 2004, or (ii) the last day of the month following the consecutive twelve (12) month period that InterMune Net Sales in the United States are equal to or greater than twenty million dollars ($20,000,000), subject to subsection (d) below.

(c) If 2001 Net Sales are less than fifteen million dollars ($15,000,000), then on March 31, 2002, InterMune shall pay to Connetics a portion of the Milestone Payment equal to three hundred thousand dollars ($300,000) multiplied by a fraction, the numerator of which is 2001 Net Sales and the denominator of which is twenty million dollars ($20,000,000). InterMune shall furnish to Connetics a promissory note for the balance of the Milestone Payment (the “Remaining Payment”), which promissory note shall provide for full payment of the balance of such note to Connetics on the earlier to occur of (i) March 31, 2004, or (ii) the last day of the month following the consecutive twelve (12) month period that InterMune Net Sales in the United States are equal to or greater than twenty million dollars ($20,000,000), subject to subsection (d) below.

(d) With respect to the promissory note for the Remaining Payment described in subsection (b) or (c) above, if InterMune is to pay the balance of such note on March 31, 2004, and InterMune Net Sales in the United States for the twelve (12) month period preceding March 31, 2004 are equal to or greater than ten million dollars ($10,000,000) but less than twenty million dollars ($20,000,000), then:

(i) InterMune may, at its election, pay fifty percent (50%) of the Remaining Payment either in cash or in Preferred Shares of InterMune stock at the fair market value of such shares, determined as the average closing price of such shares over the previous thirty (30) day period; and

(ii) With respect to the other fifty percent (50%) of the Remaining Payment, Connetics may, at its election, receive such fifty percent either in cash or in Preferred Shares of InterMune stock at the fair market value of such shares, determined as the average closing price of such shares over the previous thirty (30) day period, provided that Connetics shall notify InterMune of its election in writing at least thirty (30) days prior to the date that such payment is due.

(e) With respect to the Remaining Payment described in subsection (b) or (c) above, if InterMune is to pay the balance of such note on March 31, 2004, and InterMune Net Sales in the United States for the twelve (12) month period preceding March 31, 2004 are less than ten million dollars ($10,000,000), then InterMune may, at its election, either:

(i) Pay such Remaining Payment in cash or in Preferred Shares of InterMune stock at the fair market value of such shares, determined as the average closing price of such shares over the previous thirty (30) day period; or
Grant to Connetics the license to the Accounting and Revenue Rights to CGD Units (as defined below), on commercially reasonable terms to be agreed upon by the Parties, in which event InterMune shall thereafter have no further obligation to Connetics with respect to such Remaining Payment. Such license shall be fully paid-up solely with respect to InterMune but not with respect to Genentech or any other Third Party, and shall expire upon the date of expiration of the last to expire Genentech Patent covering the manufacture, use or sale of Licensed Products for the treatment of CGD in the United States and its territories and possessions. As used herein, “Accounting and Revenue Rights to CGD Units” means the right to book net revenues, expenses and net profits for the sales of Licensed Products for the treatment of chronic granulomatous disease by InterMune and its sublicensees in the United States.

(f) All promissory notes referred to in this Section 5.2 shall bear interest at the rate of the prime rate plus two percentage points (2%).

5.3 Reports; Audit Rights. InterMune shall provide to Connetics a copy of all reports submitted to Genentech by InterMune pursuant to Section 8.8 of the Genentech License when InterMune submits such report to Genentech. Following January 1, 2002, Connetics shall have the same audit rights as Genentech pursuant to Section 8.8 of the Genentech License.

5.4 Third Party Royalties. Each Party shall be responsible for paying all royalties due to Third Parties other than Genentech under Section 8.4 of the Genentech License with respect to such Party’s and its sublicensees’ activities hereunder.

6. INTELLECTUAL PROPERTY

6.1 Ownership of Inventions. Each Party shall remain the sole owner of its respective technology and other intellectual property that it owned as of the Effective Date. A Party shall not have or acquire any rights in any inventions, Know-How or intellectual property rights of the other Party, except as specifically granted herein.

6.2 Infringement of Third Party Patents. In the event that a Third Party files an action against a Party alleging that such Party’s activities under this Agreement infringe such Third Party’s patent rights, such Party shall give written notice to the other Party, and the Parties will consult and cooperate on the best course of action. The Party that was sued shall have the right to defend itself against such action, and the other Party shall provide all reasonable assistance in such defense.

6.3 Infringement of Licensed Patents. In the event that either Party becomes aware that a Third Party is infringing any rights in the Genentech Patents, such Party shall promptly notify the other. InterMune shall have the right to enforce the Genentech Patents to the full extent permitted under the Genentech License, and Connetics will reasonably cooperate with InterMune in such enforcement actions and take all reasonably necessary steps to facilitate InterMune’s enforcement of the Genentech Patents.

6.4 Cooperation. Each Party agrees to cooperate with the other and take all reasonable additional actions as may be reasonably required to achieve the intent of this Article
7. **Representations and Warranties**

7.1 **Mutual Representations and Warranties.** Each Party hereby represents and warrants to the other Party as follows:

(a) Such Party (i) is duly organized, validly existing and in good standing under the laws of the state in which it is organized; (ii) has the power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carry on its business as it is now being conducted; and (iii) is in compliance with all requirements of applicable law, except to the extent that any noncompliance would not materially adversely affect such Party’s ability to perform its obligations under the Agreement.

(b) Such Party (i) has the power and authority and the legal right to enter into the Agreement and to perform its obligations hereunder, and (ii) has taken all necessary action on its part to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder. The Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.

(c) All necessary consents, approvals and authorizations of all governmental authorities and other persons required to be obtained by such Party in connection with the Agreement have been obtained.

(d) The execution and delivery of the Agreement and the performance of such Party’s obligations hereunder (i) do not conflict with or violate any requirement of applicable laws or regulations or any material contractual obligation of such Party, and (ii) do not materially conflict with, or constitute a material default or require any consent under any material contractual obligation of such Party.

7.2 **Connetics Representations and Warranties.** Connetics hereby represents and warrants that:

(a) To Connetics’ knowledge as of the Effective Date, the Licensed Technology practiced as permitted herein does not infringe on any intellectual property rights owned by any Third Party.

(b) Connetics possesses the necessary interest, title and right to the Licensed Technology to grant the licenses and to make the assignments to InterMune hereunder.

8. **Indemnification**

8.1 **Indemnification by Connetics.** Connetics agrees to indemnify, hold harmless and defend InterMune and InterMune’s directors, officers, employees and agents, and the directors, officers, employees and agents of any InterMune Affiliate from and against any and all claims, suits, losses, damages, costs, fees and expenses resulting from or arising out of any
negligent or wrongful act or omission by Connetics, its Affiliates or its Dermatology Sublicensees, or any breach by Connetics of its obligations under this Agreement or under the Genentech License, except to the extent that such claims, suits, losses, damages, costs, fees or expenses arises or results from any negligent or wrongful act or omission of InterMune or its Affiliates.

8.2 Indemnification by InterMune. InterMune agrees to indemnify, hold harmless and defend Connetics and its directors, officers, employees and agents, and the directors, officers, employees and agents of any Connetics Affiliates or its Dermatology Sublicensees from and against any and all claims, suits, losses, damages, costs, fees and expenses resulting from or arising out of damage or injury caused by a negligent or wrongful act or omission of InterMune, its Affiliates or its Sublicensees, or any breach by InterMune of its obligations under this Agreement or under the Genentech License, except to the extent that such claims, suits, losses, damages, costs, fees or expenses arises or results from any negligent or wrongful act or omission of Connetics, its Affiliates or its Dermatology Sublicensees.

8.3 Indemnification Procedure. In all cases where one Party seeks indemnification by the other under this Article 8, the Party seeking indemnification shall promptly notify the indemnifying Party of receipt of any claim or lawsuit covered by such indemnification obligation and shall cooperate fully with the indemnifying Party in connection with the investigation and defense of such claim or lawsuit. The indemnifying Party shall have the right to control the defense, with counsel of its choice, provided that the non-indemnifying Party shall have the right to be represented by advisory counsel at its own expense. The indemnifying Party shall not settle or dispose of the matter in any manner which could negatively and materially affect the rights or liability of the non-indemnifying Party without the non-indemnifying Party’s prior written consent, which shall not be unreasonably withheld.

9. CONFIDENTIALITY

9.1 Confidential Information Obligations. As used herein, “Confidential Information” means all information that a Party discloses to the other Party under this Agreement or had disclosed to the other Party under the Original Agreement, provided that Confidential Information shall not include such information excluded under Section 9.2. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, during the term of this Agreement and for five (5) years after the expiration or termination of this Agreement, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement any Confidential Information furnished to it by the other Party pursuant to this Agreement.

9.2 Exceptions. The obligations set forth in Section 9.1 shall not apply to any Information that the receiving Party can demonstrate by competent evidence:

(a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party by the other Party;
became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party, other than under an obligation of confidentiality to a Third Party, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others; or

(e) is independently developed by the receiving Party without using any of the other Party’s Confidential Information.

9.3 Terms of the Agreement. The Parties agree that the terms of this Agreement will be considered Confidential Information of both Parties. Notwithstanding the foregoing, a Party shall have the right to disclose the material financial terms of the Agreement to any bona fide potential investor, investment banker, acquiror, merger partner or other potential financial partner, subject to such Party obtaining the agreement of such party receiving such Confidential Information to keep such information confidential.

9.4 Permitted Disclosure. Notwithstanding the limitations in this Article 9, each Party may disclose Confidential Information belonging to the other Party (or otherwise subject to this Article 9), to the extent such disclosure is reasonably necessary in the following instances, but solely for the limited purpose of such necessity:

(a) filing or prosecuting Patents;

(b) regulatory and tax filings;

(c) prosecuting or defending litigation;

(d) complying with applicable governmental laws or regulations or valid court orders;

(e) conducting preclinical or clinical trials of Licensed Products; and

(f) disclosure to Affiliates, licensees, sublicensees, employees, consultants or agents who agree to be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party’s Confidential Information pursuant to Section 9.4, it will give reasonable advance notice to the other Party of such disclosure and endeavor in good faith to secure confidential treatment of such information. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. Further, the Parties agree to consult with one another on the provisions of this Agreement to be redacted in any filings made by a Party with the United States Securities and Exchange Commission or as otherwise required by law.
10. **TERMINATION**

10.1 **Term of Agreement.** The term of this Agreement shall expire, unless earlier terminated as provided by Section 10.2 below, upon expiration or termination of the Genentech License.

10.2 **Termination for Material Breach.** If either Party shall default in a material manner with respect to any material provision of this Agreement and the other Party shall have given the defaulting Party written notice of such default, the defaulting Party shall have thirty (30) days to cure such default. If such default is not cured within such thirty (30) day period, the non-defaulting Party shall have the right, upon notice to the defaulting Party and without prejudice to any other rights the non-defaulting Party may have, to terminate this Agreement unless the defaulting Party is in the process of attempting in good faith to remedy such default, in which case, the thirty (30) day cure period shall be extended by an additional thirty (30) days.

10.3 **Effect of Termination.** Upon termination or expiration of the Agreement, (a) all licenses granted by Connetics to InterMune under Article 3 will terminate; (b) any and all claims and payment obligations that accrued prior to the date of such termination or expiration shall survive such termination; and (c) each Party shall return all of the other Party’s Confidential Information.

10.4 **Surviving Rights.** The obligations and rights of the Parties under Sections 4.3(c), 5.3, 6.1, and Articles 8, 9, 10 and 11 shall survive any termination or expiration of the Agreement.

10.5 **Accrued Rights and Surviving Obligations.** The termination or expiration of the Agreement for any reason shall be without prejudice to any rights, which shall have accrued to the benefit of either Party prior to such termination or expiration, including any damages arising from any breach hereunder. Such termination or expiration shall not relieve either Party from obligations which are expressly indicated to survive termination or expiration of the Agreement.

10.6 **Bankruptcy Rights.** In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy laws due to such Party’s bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code and any similar law or regulation in any other country, licenses of rights to “intellectual property” as defined under Section 101(52) of the Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, including without limitation any patents or patent applications in any country of a Party covered by the license grants under this Agreement, are part of the “intellectual property” as defined under Section 101(52) of the Bankruptcy Code subject to the protections afforded the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country.
11. MISCELLANEOUS

11.1 Waiver. No waiver by either Party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent or similar breach or default.

11.2 Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their permitted successors and assigns; provided, however, that neither Party shall assign any of its rights and obligations hereunder without the prior written consent of the other Party, except as incident to the merger, consolidation, reorganization or acquisition of stock or assets affecting substantially all of the assets or actual voting control of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 11.2 shall be null and void and of no legal effect.

11.3 Notices. Any notice or other communication required or permitted to be given to either Party hereto shall be in writing and shall be deemed to have been properly given and to be effective on the date of delivery if delivered in person or by facsimile or five (5) days after mailing by registered or certified mail, postage paid, to the other Party at the following address:

In the case of InterMune:
InterMune Pharmaceuticals, Inc.
1710 Gilbreth Road,
Suite 301
Burlingame, CA 94010
Fax: (650) 259-0774
Attention: General Counsel

with a copy to:
Cooley Godward LLP
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306
Fax: (650) 849-7400
Attention: Barclay James Kamb, Esq

In the case of Connetics:
Connetics Corporation
3400 West Bayshore Road
Palo Alto, CA 94303
Fax: (650) 843-2899
Attention: Chief Executive Officer

Either Party may change its address for communications by a notice to the other Party in accordance with this Section.

11.4 Headings. The headings of the several sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.
11.5 Amendment. No amendment or modification hereof shall be valid or binding upon the Parties unless made in writing and signed by both Parties.

11.6 Governing Law. This Agreement shall be governed exclusively by the laws of the State of California, U.S.A., as such law applies to contracts entered into between and to be performed by California residents entirely in the State of California.

11.7 Dispute Resolution.

(a) In the event of any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, or the rights or obligations of the Parties hereunder, the Parties shall try to settle their differences amicably between themselves by referring the disputed matter to the President of InterMune and the Chief Executive Officer of Connetics for discussion and resolution. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within ten (10) days after such notice such representatives of the Parties shall meet for attempted resolution by good faith negotiations. If such personnel are unable to resolve such dispute within thirty (30) days of initiating such negotiations, either Party may seek to have such dispute resolved by binding arbitration under this Section 11.7. The arbitration shall be held in Palo Alto, California according to the Commercial Arbitration Rules of the American Arbitration Association (the “Rules”). The arbitration will be conducted by a panel of three (3) arbitrators who are knowledgeable in the subject matter that is at issue in the dispute, are not affiliated directly or indirectly with either Party, and are selected by mutual agreement of the Parties. Failing such agreement, the arbitrators shall be selected appointed as provided in the Rules. During the arbitration, the Parties shall have such discovery rights as the arbitrators may allow, consistent with the discovery permitted by the Federal Code of Civil Procedure. In conducting the arbitration, the arbitrators shall apply the rules of evidence applicable in California, and shall be able to decree any and all relief of an equitable nature, including but not limited to such relief as a temporary restraining order, a preliminary injunction, a permanent injunction, or replevin of property, as well as specific performance. The arbitrators shall also be able to award direct and indirect damages, but shall not award any other form of damage (e.g., punitive or exemplary damages). The reasonable fees and expenses, of the arbitrators, along with the reasonable legal fees and expenses of the prevailing Party (including all expert witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows: If the arbitrators rule in favor of one Party on all disputed issues in the arbitration, the losing Party shall pay one hundred percent (100%) of such fees and expenses; if the arbitrators rule in favor of one Party on some issues and the other Party on other issues, the arbitrators shall issue with the rulings a written determination as to how such fees and expenses shall be allocated between the Parties. The arbitrators shall allocate fees and expenses in a way that bears a reasonable relationship to the outcome of the arbitration, with the Party prevailing on more issues, or on issues of greater value or gravity, recovering a relatively larger share of its legal fees and expenses. The decision of the arbitrators shall be final and may be entered, sued on or enforced by the Party in whose favor it runs in any court of competent jurisdiction at the option of such Party. Whether a claim, dispute or other matter in question would be barred by the applicable statute of limitations, which statute of limitations also shall apply to any claim or disputes subject to arbitration under this Section, shall be determined by binding arbitration pursuant to this Section.
Notwithstanding anything to the contrary in this Agreement, either Party may seek immediate injunctive or other interim relief without resort to arbitration from any court of competent jurisdiction with respect to any breach of Article 9 hereof, or as necessary to enforce and prevent infringement of the patent rights, copyright rights, trademarks, trade secrets, or other intellectual property rights owned or controlled by a Party or its Affiliates.

11.8 Force Majeure. Any delays in performance by any Party under this Agreement shall not be considered a breach of this Agreement if and to the extent caused by occurrences beyond the reasonable control of the Party affected, including but not limited to acts of God, embargoes, governmental restrictions, fire, flood, explosion, riots, wars, civil disorder, rebellion or sabotage. The Party suffering such occurrence shall immediately notify the other Party as soon as practicable, and any time for performance hereunder shall be extended by the actual time of delay caused by the occurrence.

11.9 Independent Contractors. In making and performing this Agreement, InterMune and Connetics act and shall act at all times as independent contractors and nothing contained in this Agreement shall be construed or implied to create an agency, partnership or employer and employee relationship between InterMune and Connetics. At no time shall one Party make commitments or incur any charges or expenses for or in the name of the other Party.

11.10 Severability. If any part of this Agreement is declared invalid by any legally governing authority having jurisdiction over either Party, then such declaration shall not affect the remainder of the Agreement and the Parties shall revise the invalidated part in a manner that will render such provision valid without impairing the Parties’ original interest.

11.11 Cumulative Rights. The rights, powers and remedies hereunder shall be in addition to, and not in limitation of, all rights, powers and remedies provided at law or in equity, or under any other agreement between the Parties. All of such rights, powers and remedies shall be cumulative, and may be exercised successively or cumulatively.

11.12 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be an original and all of which shall constitute together the same document.

11.13 Entire Agreement. This Agreement and any and all Exhibits referred to herein, in conjunction with the other “Intercompany Agreements” (as defined in that certain Collaboration Agreement by and between the Parties dated April 27, 1999 excluding the “Amended and Restated Service Agreement”), embodies the entire understanding of the Parties with respect to the subject matter hereof and of the “Intercompany Agreements,” and supersedes and terminates all previous communications, representations or understandings, either oral or written, between the Parties relating to the subject matter hereof and of the “Intercompany Agreements.” The Amended and Restated Service Agreement is hereby terminated in its entirety, except for the provisions of the sections set forth in Section 14 therein.
IN WITNESS WHEREOF, both InterMune and Connetics have executed this Agreement, as of the day and year first written above.

INTERMUNE PHARMACEUTICALS, INC.

By: /s/ S. Scott Harkonen
Print Name: W. Scott Harkonen
Title: Pres/CEO

CONNETICS CORPORATION

By: Thomas G. Wiggans
Print Name: Thomas G. Wiggans
Title: President & CEO
REVENUE ADJUSTMENT AGREEMENT

BY AND BETWEEN

INTERMUNE PHARMACEUTICALS, INC.

AND

CONNETICS CORPORATION

JUNE 27, 2000
REVENUE ADJUSTMENT AGREEMENT

THIS REVENUE ADJUSTMENT AGREEMENT (the “Agreement”) is made effective and entered into as of June 27, 2000 (the “Effective Date”) by and between Connetics Corporation, a Delaware corporation, with its principal place of business at 3400 West Bayshore Road, Palo Alto, CA 94303 (“Connetics”), and InterMune Pharmaceuticals, Inc., a Delaware corporation, with its principal place of business at 1710 Gilbreth Road, Suite 301, Burlingame, CA 94010 (“InterMune”). Connetics and InterMune may be referred to herein as a “Party” or collectively as the “Parties.”

RECITALS

A. WHEREAS, the Parties have entered into that certain Collaboration Agreement, dated as of April 27, 1999 (the “Collaboration Agreement”), by which, among other provisions, InterMune became obligated to pay to Connetics: (i) a $500,000 milestone payment on or before March 31, 2001; and (ii) a $1.5 million milestone payment on or before March 31, 2002;

B. WHEREAS, The Parties have entered into that certain Assignment and Option Agreement, dated as of June 23, 2000 (the “Assignment Agreement”), pursuant to which, among other provisions: (i) Connetics assigned to InterMune Connetics’ entire right, title and interest in, to and under that certain License Agreement for Interferon Gamma by and between Connetics and Genentech, Inc. (“Genentech”) dated May 5, 1998, as amended (the “Genentech License”) and (ii) InterMune affirmed its obligation to pay to Connetics the $1.5 million milestone payment pursuant to the Collaboration Agreement;

C. WHEREAS, the Parties have entered into that certain Transition Agreement, dated as of April 27, 1999 (the “Transition Agreement”), by which, among other provisions, the parties have set forth certain rights and obligations with respect to the revenue from the sales of Actimmune®;

D. WHEREAS, by this Amendment, the Parties now desire to delete Section 5.2 of the Assignment Agreement and terminate the Collaboration Agreement and Transition Agreement (each generally, an “Original Agreement,” and collectively, the “Original Agreements”) as set forth herein in order to adjust the Parties’ rights and obligations with respect to the revenue from the sales of Actimmune.

NOW, THEREFORE, in consideration of the foregoing recitals and mutual promises hereinafter set forth, the Parties agree as follows:

1. DEFINITIONS.

1.1 Actimmune. “Actimmune” means the filled and finished form of the protein encoded by the interferon gamma-1b gene, and sold and distributed under the trademark ACTIMMUNE®, which is owned by Genentech and licensed to Connetics and its sublicenses under the Genentech License.

1.2 Actimmune Gross Margin. “Actimmune Gross Margin” means Actimmune Net Sales less all applicable Product Cost of Actimmune Units sold, GNE Royalties, third party
royalties payable pursuant to Section 8.4 of the Genentech License and CORD Distribution Costs.

1.3 Actimmune Gross Sales. “Actimmune Gross Sales” means all revenue recorded in connection with shipments of Actimmune Units multiplied by the price per Actimmune Unit, including revenue with associated accounts receivable for accounting purposes for specific shipment/invoicing transactions with respect to Actimmune Units, and assumes that invoices are prepared immediately following notification of shipment of goods, and are dated the same day of shipment.

1.4 Actimmune Net Sales. “Actimmune Net Sales” means Actimmune Gross Sales less adjustments for the following: product returns, Medicare and Medicaid reimbursements, chargebacks, rebates, state payments, other contractual reimbursement, and cash discounts.

1.5 Actimmune Units. “Actimmune Units” means vials of ACTIMMUNE® that are sold as commercial product by InterMune in an arm’s length transaction.

1.6 CORD Distribution Costs. “CORD Distribution Costs” means the actual payment by InterMune to CORD Logistics, Inc., for distribution services for sales of Actimmune.

1.7 GNE Royalties. “GNE Royalties” means the amount of royalties payable to Genentech, Inc. pursuant to section 8.3 of the Genentech License for Actimmune Net Sales.

1.8 Product Management Costs. “Product Management Costs” means InterMune’s actual costs to manage sales of Actimmune Units, including all expenses and services related to sales of such Actimmune Units, such as maintenance of safety databases, etc., tracked on a regular basis and properly accounted for.

2. AMENDMENT OF ASSIGNMENT AGREEMENT.

Section 5.2 of the Assignment Agreement is deleted in its entirety. Section 5.1 of the Assignment Agreement is unaffected by this Agreement.

3. TERMINATION OF COLLABORATION AGREEMENT.

The Collaboration Agreement is terminated in its entirety.

4. TERMINATION OF TRANSITION AGREEMENT.

The Transition Agreement is terminated in its entirety.

5. INTERMUNE PAYMENTS TO CONNETICS.

5.1 June 30, 2000. On June 30, 2000, InterMune shall be obligated to pay and shall pay $5,218,172 to Connetics; provided however, InterMune shall be credited $484,305 toward this payment.

6. Revenue Recognition.

For the fiscal quarter beginning April 1 and ending June 30, 2000, and without regard to the Effective Date of this Agreement, InterMune shall be entitled to book and recognize Actimmune Net Sales for sales of all Actimmune Units and the Actimmune Gross Margin. Effective July 1, 2000, InterMune shall be entitled to book and recognize all revenues, sales, margins, etc. from the sales of Actimmune.

7. Obligations to Third Parties and Indemnification of Connetics.

InterMune hereby affirms its obligations pursuant to Section 2.5 of the Transition Agreement and Section 5.4 of the Assignment Agreement to remit to Genentech any accounts payable on Actimmune Net Sales for third-party royalties and for GNE Royalties, all as required by the Genentech License. InterMune affirms its covenant and agreement to remit the full amount of such royalties directly to Genentech or the applicable third party, and shall indemnify Connetics against any action by Genentech or such third party to collect royalties for Actimmune Unit Sales made after April 27, 1999.

8. Confidentiality.

8.1 Confidential Information Obligations. As used herein, “Confidential Information” means all information that a Party discloses to the other Party under this Agreement or had disclosed to the other Party under the Original Agreement, provided that Confidential Information shall not include such information excluded under Section 8.2. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, during the term of this Agreement and for five (5) years after the expiration or termination of this Agreement, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement any Confidential Information furnished to it by the other Party pursuant to this Agreement, the Collaboration Agreement and/or the Transition Agreement.

8.2 Exceptions. The obligations set forth in Section 8.1 shall not apply to any Information that the receiving Party can demonstrate by competent evidence:

(a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party by the other Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;
was disclosed to the receiving Party, other than under an obligation of confidentiality to a third party, by a third party who had no obligation to the disclosing Party not to disclose such information to others; or
(e) is independently developed by the receiving Party without using any of the other Party’s Confidential Information.

8.3 Terms of the Agreement. The Parties agree that the terms of this Agreement will be considered Confidential Information of both Parties. Notwithstanding the foregoing, a Party shall have the right to disclose the material financial terms of the Agreement to any bona fide potential investor, investment banker, acquirer, merger partner or other potential financial partner, subject to such Party obtaining the agreement of such party receiving such Confidential Information to keep such information confidential.

8.4 Permitted Disclosure. Notwithstanding the limitations in this Section 8, each Party may disclose Confidential Information belonging to the other Party (or otherwise subject to this Section 8), to the extent such disclosure is reasonably necessary in the following instances, but solely for the limited purpose of such necessity:
(a) filing or prosecuting patents;
(b) regulatory and tax filings;
(c) prosecuting or defending litigation;
(d) complying with applicable governmental laws or regulations or valid court orders; and
(e) disclosure to a party’s affiliates, licensees, sublicensees, employees, consultants or agents who agree to be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 8.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party’s Confidential Information pursuant to this Section 8.4, it will give reasonable advance notice to the other Party of such disclosure and endeavor in good faith to secure confidential treatment of such information. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. Further, the Parties agree to consult with one another on the provisions of this Agreement to be redacted in any filings made by a Party with the United States Securities and Exchange Commission or as otherwise required by law.

9. TERMINATION.

9.1 Term of Agreement. The term of this Agreement shall expire upon InterMune’s payment of the full amounts to Connetics pursuant to Sections 5.1 and 5.2.

9.2 Termination for Material Breach. If either Party shall default in a material manner with respect to any material provision of this Agreement and the other Party shall have
given the defaulting Party written notice of such default, the defaulting Party shall have thirty (30) days to cure such default. If such default is not cured within such thirty (30) day period, the non-defaulting Party shall have the right, upon notice to the defaulting Party and without prejudice to any other rights the non-defaulting Party may have, to terminate this Agreement unless the defaulting Party is in the process of attempting in good faith to remedy such default, in which case, the thirty (30) day cure period shall be extended by an additional thirty (30) days.

9.3 Surviving Rights. The obligations and rights of the Parties under Sections 7, 8, 9, 10.3, 10.6, 10.7, and 10.11 shall survive any termination or expiration of the Agreement.

9.4 Accrued Rights and Surviving Obligations. The termination or expiration of the Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to such termination or expiration, including any damages arising from any breach hereunder. Such termination or expiration shall not relieve either Party from obligations, which are expressly indicated to survive termination or expiration of the Agreement.

9.5 Bankruptcy Rights. In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy laws due to such Party’s bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code and any similar law or regulation in any other country, licenses of rights to “intellectual property” as defined under Section 101(52) of the Bankruptcy Code.

10. MISCELLANEOUS.

10.1 Waiver. No waiver by either Party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent or similar breach or default.

10.2 Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their permitted successors and assigns; provided, however, that InterMune may not assign any of its rights and obligations hereunder without the prior written consent of Connetics, except as incident to the merger, consolidation, reorganization or acquisition of stock or assets affecting substantially all of the assets or actual voting control of InterMune. Any assignment or attempted assignment by InterMune in violation of the terms of this Section 10.2 shall be null and void and of no legal effect.

10.3 Notices. Any notice or other communication required or permitted to be given to either Party hereto shall be in writing and shall be deemed to have been properly given and to be effective on the date of delivery if delivered in person or by facsimile or five (5) days after mailing by registered or certified mail, postage paid, to the other Party at the following address:

In the case of InterMune:

InterMune Pharmaceuticals, Inc.
1710 Gilbreth Road,
Suite 301
Burlingame, CA 94010
Fax: (650) 259-0774

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Either Party may change its address for communications by a notice to the other Party in accordance with this Section.

10.4 **Headings.** The headings of the several sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

10.5 **Amendment.** No amendment or modification hereof shall be valid or binding upon the Parties unless made in writing and signed by both Parties.

10.6 **Governing Law.** This Agreement shall be governed exclusively by the laws of the State of California as such law applies to contracts entered into between and to be performed by California residents entirely in the State of California.

10.7 **Dispute Resolution.**

(a) In the event of any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, or the rights or obligations of the Parties hereunder, the Parties shall try to settle their differences amicably between themselves by referring the disputed matter to the President of InterMune and the Chief Executive Officer of Connetics for discussion and resolution. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within ten (10) days after such notice such representatives of the Parties shall meet for attempted resolution by good faith negotiations. If such personnel are unable to resolve such dispute within thirty (30) days of initiating such negotiations, either Party may seek to have such dispute resolved by binding arbitration under this Section 10.7. The arbitration shall be held in Palo Alto, California according to the Commercial Arbitration Rules of the American Arbitration Association (the “Rules”). The arbitration will be conducted by a panel of three arbitrators who are knowledgeable in the subject matter that is at issue in the dispute, are not affiliated directly or indirectly with either Party, and are selected by mutual agreement of the Parties. Failing such agreement, the arbitrators shall be selected appointed as provided in the Rules. During the arbitration, the Parties shall have such discovery rights as the arbitrators may allow, consistent with the discovery permitted by the Federal Code of Civil Procedure. In conducting the
arbitration, the arbitrators shall apply the rules of evidence applicable in California, and shall be able to decree any and all relief of an equitable nature, including but not limited to such relief as a temporary restraining order, a preliminary injunction, a permanent injunction, or replevin of property, as well as specific performance. The arbitrators shall also be able to award direct and indirect damages, but shall not award any other form of damage (e.g., punitive or exemplary damages). The reasonable fees and expenses, of the arbitrators, along with the reasonable legal fees and expenses of the prevailing Party (including all expert witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows: If the arbitrators rule in favor of one Party on all disputed issues in the arbitration, the losing Party shall pay one hundred percent (100%) of such fees and expenses; if the arbitrators rule in favor of one Party on some issues and the other Party on other issues, the arbitrators shall issue with the rulings a written determination as to how such fees and expenses shall be allocated between the Parties. The arbitrators shall allocate fees and expenses in a way that bears a reasonable relationship to the outcome of the arbitration, with the Party prevailing on more issues, or on issues of greater value or gravity, recovering a relatively larger share of its legal fees and expenses. The decision of the arbitrators shall be final and may be entered, sued on or enforced by the Party in whose favor it runs in any court of competent jurisdiction at the option of such Party. Whether a claim, dispute or other matter in question would be barred by the applicable statute of limitations, which statute of limitations also shall apply to any claim or disputes subject to arbitration under this Section, shall be determined by binding arbitration pursuant to this Section.

(b) Notwithstanding anything to the contrary in this Agreement, either Party may (without resort to arbitration) seek immediate injunctive or other interim relief from any court of competent jurisdiction with respect to any breach of Section 9 hereof, or as necessary to enforce and prevent infringement of the patent rights, copyright tights, trademarks, trade secrets, or other intellectual property rights owned or controlled by a Party or its Affiliates.

10.8 Force Majeure. Any delays in performance by any Party under this Agreement shall not be considered a breach of this Agreement if and to the extent caused by occurrences beyond the reasonable control of the Party affected, including but not limited to acts of God, embargoes, governmental restrictions, fire, flood, explosion, riots, wars, civil disorder, rebellion or sabotage. The Party suffering such occurrence shall immediately notify the other Party as soon as practicable, and any time for performance hereunder shall be extended by the actual time of delay caused by the occurrence.

10.9 Severability. If any part of this Agreement is declared invalid by any legally governing authority having jurisdiction over either Party, then such declaration shall not affect the remainder of the Agreement and the Parties shall revise the invalidated part in a manner that will render such provision valid without impairing the Parties’ original interest.

10.10 Cumulative Rights. The rights, powers and remedies hereunder shall be in addition to, and not in limitation of, all rights, powers and remedies provided at law or in equity, or under any other agreement between the Parties. All of such rights, powers and remedies shall be cumulative, and may be exercised successively or cumulatively.
10.11 **Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be an original and all of which shall constitute together the same document.

10.12 **Entire Agreement.** This Agreement embodies the entire understanding of the Parties with respect to the subject matter hereof and supersedes and terminates all previous communications, representations or understandings, either oral or written, between the Parties relating to the subject matter hereof.
IN WITNESS WHEREOF, both InterMune and Connetics have executed this Agreement, as of the day and year first written above.

INTERMUNE PHARMACEUTICALS, INC.

By: /s/ Scott Harkonen
Print Name: Scott Harkonen
Title: Pres. & CEO

CONNETICS CORPORATION

By: /s/ Thomas G. Wiggans
Print Name: Thomas G. Wiggans
Title: President & CEO
Dated the 16th day of April 2012

BENTON PROPERTY HOLDING LIMITED (IN RECEIVERSHIP) (1)

and

JIM HAMILTON (2)

and

VIDARA THERAPEUTICS (3)

LICENCE AGREEMENT

Re: Unit Nos. 202 and 203
Second Floor
Adelaide Chambers
Peter Street
Dublin 8

Eversheds O’Donnell Sweeney
Solicitors
One Earlsfort Centre
Earlsfort Terrace
Dublin 2
THIS AGREEMENT is made on 16/04/2012

BETWEEN:

(1) BENTON PROPERTY HOLDING LIMITED (IN RECEIVERSHIP) (company registration number 234144) having its registered office at Adelaide Chambers, Peter Street, Dublin 8 (“the Licensor” which expression shall include its successors and assigns) of the first part

(2) JIM HAMILTON of Beaux Lane House, Mercer Street Lower, Dublin 2 (the “Receiver”) of the second part; and

(3) VIDARA THERAPEUTICS of Unit No. 202/203, Second Floor Adelaide Chambers, Peter Street, Dublin 8 (hereinafter called the “Licensee”) of the third part.

WHEREAS:-

A. The Licensor is the owner of the building known as Adelaide Chambers, Peter Street, Dublin 8 (the “Building”).

B. Pursuant to the terms of a Mortgage dated 12 December 2003 between the Licensor (1) and Irish Nationwide Building Society (2), the Receiver was appointed on 21 October 2010 to the Building.

C. The Licensee would like to use the area in the Building known or to be known as Unit Nos. 202 and 203, Second Floor Adelaide Chambers, Peter Street, Dublin 8 (the “Licensed Area”)

D. The Licensor acting by the Receiver has agreed strictly subject to the conditions herein contained to licence to the Licensee Area to be used strictly on the terms hereinafter appearing.

IT IS AGREED by and between the parties hereto as follows:-

1 INTERPRETATION

1.1 In this Agreement the following expressions shall have the following meanings:-

Definitions

“Insured Risks” means the risks and perils against which the Licensor acting by the Receiver shall at the time of the damage or destruction in question have effected insurance subject always to such exclusions terms excesses and limitations as are generally available or as may be imposed by the insurers for the time being and including without limitation if so determined by the Licensor acting by the Receiver insurance against fire lightning explosion storm tempest flood landslip heave subsidence bursting or overflowing of water tanks apparatus or pipes impact aircraft or other aerial devices or articles dropped or falling therefrom riots civil commotion malicious damage to underground services employers, public liability, and engineering and contents insurances and such other risks and perils as the Licensor acting by the Receiver shall in its discretion from time to time consider necessary subject in the case of each and all such risks and perils to the availability of insurance cover against the same at a cost which in the opinion of the Licensor acting by the Receiver is not excessive and to the extent that and subject to such terms and conditions as insurance cover against each and all such risks and perils is available;
“Licence” the licence for the Licensee to enter upon and to use the Licensed Area, together with the rights as set out in the First Schedule in common with the Licensor and all others authorised by the Licensor;

“Licence Fee” means the sum of seven thousand and ninety eight Euro (€7,098) per annum;

“Licence Fee Commencement Date” the date hereof;

“Licence Period” the period of one (1) year from the date hereof;

“Permitted Use” means use as offices;

“Prescribed Rate” means twelve per centum (12%) per annum or at the discretion of the Licensor six per centum (6%) above the 3 month EURIBOR meaning;

The rate per annum from time to time determined at the election of the Licensor by either Allied Irish Banks plc or Bank of Ireland (which shall include their respective successors) calculated by reference to the rate at which Euro interbank Licence Period deposits for a 3 month period (quoted for spot value on an adjusted 365 day count basis) are being offered within the EMU zone by one prime bank to another at 11.00 am Brussels time or if there is no such rate the nearest or corresponding rate thereto as determined by the Licensor acting reasonably;

“Quarterly Payment Days” means the first day of January, first day of April, first day of July and first day of October in every year;

“Relevant Laws” all national, European and international laws, codes, directives and regulations having legal force or effect for the time being in Ireland and all other directions made by any competent local, public or statutory authority relating to or affecting the use or operation of the Licensed Area, the health and safety of persons therein or otherwise directly or indirectly relating to or affecting the occupation, use and operation of the Licensed Area and without prejudice to the generality of the foregoing including all planning legislation from time to time;

“Services” means all and any services facilities and other matters provided by the Licensor acting by the Receiver from time to time for the common or general use or for the benefit of some or all of the tenants, licensees and occupiers of the Building and if appropriate to visitors of the Building;

“Service Charge” means the sum of €6.00 (exclusive of VAT) per square foot of the Licensed Area as a contribution towards the costs of carrying out and providing the Services subject to such increase or decrease as the Licensor may reasonably determine having regard to the cost of providing the Services;

“Working Day” has the meaning assigned to that term in the Lease;

1.2 Interpretation

In this Licence unless inconsistent with the context:

1.2.1 words importing the singular include the plural and vice versa;
1.2.2 words importing the masculine include the feminine and the neuter genders and vice versa;
1.2.3 words importing persons shall include firms and companies and corporations and vice versa;
1.2.4 where a party consists of more than one person covenants and obligations of that party shall be deemed to be made jointly and severally;
1.2.5 any reference to a clause or schedule means a clause or a schedule to this Licence;
1.2.6 any reference to a statute or section of a statute includes any statutory amendment modification or re-enactment of it for the time being in force and every instrument order notice direction regulation bye-law permission or condition being made or issued under it or deriving validly from it from time to time;
1.2.7 if any provision in this Licence is held to be illegal void invalid or unenforceable for any reason the legality validity and enforceability of the remainder of this Licence shall not be affected;
1.2.8 an obligation of the Licensee not to do any act matter or thing includes an obligation not to cause permit or suffer the doing of it.

2 GRANT OF LICENCE

2.1 Licence

In consideration of the covenants on the part of the Licensee herein contained the Licensor acting by the Receiver hereby grants a licence to the Licensee during the Licence Period to use the Licensed Area for the purpose of carrying on the Permitted Use (and for no other purpose), together with the rights set out in the Schedule 1 (in common with the Licensor and all others authorised from time to time), upon the terms and conditions hereinafter appearing.

2.2 Variation

The Licensor acting by the Receiver hereby reserves the right from time to time during the Licence Period to change or move the location of the Licensed Area or a part or parts thereof to such other reasonably comparable part of the Building by serving three (3) months written notice on the Licensee of its intention to do so, specifying the area or areas of the new space in the Building and the Licensee shall at its own expense on the expiration of the said notice move to such new location or locations in which event all references in this Licence to the Licensed Area and all terms and conditions of this Licence shall be deemed to apply to such new area or areas and any other area or areas subsequently allocated instead of it in accordance with this clause.

2.3 Personal Licence

This Licence is personal to the Licensee and is therefore not transferable or disposable in any way and nothing herein contained shall create or be deemed to create any relationship of landlord and tenant between the Licensor and the Licensee.

3 COVENANTS BY THE LICENSEE
The Licensee hereby covenants with the Licensor and the Receiver as follows:

3.1 to pay to the Licensor during the Licence Period from the Licence Fee Commencement Date yearly and proportionately for any fraction of a year the Licence Fee, to be paid (at the option of the Licensor which said option may be exercised on any number of occasions) either by standing order, direct debit, credit transfer or cheque by equal quarterly payments in advance on the Quarterly Payment Days without any deduction, set-off or counterclaim whatsoever;

3.2 to be responsible for all rates, taxes, assessments, duties, charges, impositions and all other such outgoings properly payable in respect of the Licensed Area or arising out of the Licensee's use and occupation of the Licensed Area and if the Licensed Area is not separately rated then to pay a fair proportion of any such items which relate to the Licensed Area and to keep the Licensor and the Receiver indemnified against any non-payment or breach thereof;

3.3 to pay the proportion applicable to the Licensed Area of the total premiums and other costs and expenses paid or to be paid by the Licensor acting by the Receiver in maintaining and keeping insurance cover against the Insured Risks for the Building such proportion to be calculated by the Licensor's surveyor (whose certificate in this respect shall be final and binding save for manifest error) together with the amount of any increased or loaded premium relating to the Licensed Area or any adjoining or neighbouring premises and to cover the loss of the Licence Fee and Service Charge payable for the Licensed Area or payable because of the history of claims in respect of the Licensed Area or because of any failure to implement the requirements and recommendations of the insurers with regard to the Licensed Area, such insurance contribution to be paid by the Licensee on demand, without any deduction, abatement, set off or counterclaim;

3.4 to pay all charges for electricity, gas, water, telephone and other such utilities incurred by the Licensee (if any) relating to the Licensed Area;

3.5 to pay to the Licensor during the Licence Period yearly and proportionately for any fraction of a year the Service Charge to be paid in advance on the Quarterly Payment Days and at the option of the Licensor which said option may be exercised on any number of occasions either by standing order, direct debit, credit transfer or cheque, without any deduction, set off or counterclaim;

3.6 not to carry out any alterations or additions whatsoever to the Licensed Area, nor to install any fixtures, fittings, furniture or equipment therein without first obtaining the prior written consent of the Licensor;

3.7 to keep the Licensed Area clean and tidy and in good order repair and condition at all times during the Licence Period and all additions and alterations thereto and all fixtures and fittings therein (damage by any of the Insured Risks excepted if and so long only as the policy or policies of insurance shall not have been vitiated or payment of the policy monies withheld or refused in whole or in part by reason of any act, neglect or default of the Licensee or the servants, agents, licensees of the Licensee) and to keep the Licensor and the Receiver effectually indemnified against all claims in respect thereof;

3.8 not to erect any signage, advertisement or notice on or within the Building without the prior written consent of the Licensor acting by the Receiver and not to affix or display in the windows of the Licensed Area any advertisement, poster, notice or other sign or thing whatsoever;

3.9 to permit the Licensor or his agent at all reasonable times (subject to reasonable prior notice save in the case of emergency) to enter the Licensed Area for all purposes connected with the rights
reserved over the Licensed Area specified in Schedule 2 and to examine the state of repair and condition thereof and to repair and make good all defects of which notice in writing shall be given by the Licensor acting by the Receiver to the Licensee and for which the Licensee is liable under the provisions hereof within one month after the giving of such notice and on the failure to comply with such notice the Licensor may carry out the work referred to therein and recover the cost thereof on demand from the Licensee as liquidated damages.

3.10 to conduct, manage and ensure the proper and efficient operation of its business from the Licensed Area and to control its staff and visitors in the Licensed Area and not to place its fixtures or fittings or any displays or signs in any of the common areas of the Building other than in the Licensed Area and then only as permitted hereunder;

3.11 to ensure that no dangerous or offensive matter or material is brought into the Building (including pets or other animals) and not to do or allow to be done any act or thing which is likely to be, or to become a nuisance, danger or annoyance to the Licensor, the Receiver or other occupiers of the Building;

3.12 to ensure health and safety at work for all staff and invitees of the Licensee in the Licensed Area and to report immediately to the Licensor any event which causes a risk to health and safety;

3.13 to effect and maintain all policies of insurance against occupiers liability, public liability, employers liability and against such other risks and liabilities as would be usually effected and maintained for a business such as the Permitted Use or as the Licensor acting by the Receiver may otherwise reasonably direct the Licensee to insure against and if reasonably directed by the Licensor acting by the Receiver to vary or extend such policies of insurance including the terms, risks and levels of cover;

3.14 to indemnify the Licensor and the Receiver (and any other person having any estate or interest in the Building or any part thereof from time to time) and keep the Licensor and the Receiver and any such person fully and effectually indemnified from and against any breach non-performance or non-observance of any of the provisions, stipulations or conditions contained in this License and against the breach non performance or non-observance of any of the rules and regulations made pursuant to or contemplated by the provisions of this Licence and from and against any claim loss injury or damage which the Licensee is obliged to insure against under clause 3.13 hereof.

3.15 to produce to the Licensor acting by the Receiver on reasonable demand, evidence that all insurances are in place in compliance with and to give full effect to the insuring obligations of and the indemnities given by the Licensee in this Licence.

3.16 to comply with all recommendations or requirements notified to it by the Licensor acting and the Receiver in relation to fire and safety precautions for the Building and to indemnify the Licensor and the Receiver (and any other person having any estate or interest in the Building or any part thereof from time to time) and keep the Licensor and the Receiver and any such person fully and effectually indemnified against any costs, loss or damage which it suffers as a result of the failure of the Licensee to comply with such recommendations and/or requirements.

3.17 to ensure that nothing is done or omitted on the Licensed Area which causes the Licensor, the Receiver or the Licensee to be in breach of any Relevant Laws or the Licensor’s insurance policy relating to or affecting the Building.
3.18 not to allow any person other than the Licensee or the Licensor (or persons expressly authorised by the Licensor) or those envisaged by the Licence herein to have possession, occupation or use of the Licensed Area;

3.19 in exercising its rights and obligations hereunder to cause as little damage or disruption and inconvenience as possible to the tenants and occupiers of the Building and not to use the Licensed Area in any manner which interferes with the use or enjoyment of the Building;

3.20 to immediately deliver (on receipt thereof) to the Licensor a copy of every notice, order, direction or any other thing whatsoever given or made or issued to the Licensee during the Licence Period by any competent authority affecting the Building or any part of it and to join in making such representations in respect thereof as the Licensor may require;

3.21 on the termination of this Licence forthwith to cease to enter or use the Licensed Area and immediately prior to the termination of this Licence to remove (unless otherwise requested by the Licensor or its agents) all the Licensee’s goods, fixtures and fittings from the Licensed Area, making good any damage so caused as soon as possible thereafter to ensure full reinstatement of the Licensed Area to the condition of same prior to the Commencement Date;

3.22 to pay interest at the Prescribed Rate upon the amount of any sum unpaid by the Licensee seven (7) days after it becomes due under the terms of this Licence such interest being payable in respect of the period from the date when any such sum falls due until the date of actual payment thereof (calculated daily, before and after any judgment);

3.23 to indemnify and keep the Licensor (and any other person having any estate or interest in the Centre or any part thereof from time to time) fully and effectually indemnified from and against all losses liabilities damages costs expenses actions claims proceedings and demands which may be suffered by or recovered or made or claimed against the Licensor and the Receiver (and any other person having any estate or interest in the Centre or any part thereof from time to time) by any person in respect of any death or injury to any person or the loss or damage of any property of any person arising directly or indirectly from or in connection with:-

(i) the use or occupation of the Licensed Area or the use of any appliances or equipment therein;

(ii) the state of repair or condition of the Licensed Area;

(iii) the making by or on behalf of the Licensee or other occupiers of any alteration addition or improvement to the Licensed Area or the state of repair or condition of any such alteration addition or Improvement;

(iv) any work carried out or in the course of being carried out by or for the Licensee or other occupiers;

(v) anything now or hereafter attached by the Licensee or other occupiers to or projecting from the Licensed Area or any other cause whatsoever arising from or in connection with the Licensed Area for which the Licensee is or are responsible or the exercise of the rights and easements granted by this Licensee.

4 GENERAL
4.1 Termination

4.1.1 The Licensor acting by the Receiver may at any time terminate this Licence on written notice with immediate effect:

(a) if any sum due hereunder is in arrears for 14 days;

(b) if the Licensee commits a breach of any of the terms of this Licence or any other misconduct on the part of the Licensee which has not been remedied within 14 days of written notice from the Licensor setting out the said breach;

(c) if the Licensee enters into liquidation or bankruptcy or suffers a receiver to be appointed to it or to any of its assets or there is presented a petition to have an examiner or interim examiner appointed in relation to it or makes a composition or arrangement with any of its creditors or if the Licensee is unable to pay its debts within the meaning of Section 214, Companies Act, 1963 or has a bankruptcy petition presented against him or is adjudged bankrupt; and/or

(d) if the Licensor or Licensee is at any time notified by any statutory body or is required pursuant to any Relevant Laws to vacate the Licensed Area;

4.1.2 The Licensee may terminate this Licence upon three (3) months notice in writing to the Licensor acting by the Receiver at any time during the Licence Period.

4.1.3 Termination in accordance with Clause 4.1 and Clause 4.2 shall be without prejudice to the rights and remedies of either party accrued prior to such termination, and shall not relieve the Licensee from any antecedent covenant or obligation under this Licence.

4.1.4 Until payment of all money due to the Licensor from the Licensee on any account, the Licensor acting by the Receiver shall have a lien on any assets of the Licensee in or on the Licensed Area.

4.1.5 If the Licence hereby set out should continue beyond the Licence Period it shall, in the absence of a new licence agreement, be deemed to be a licence determinable by seven days notice in writing to be given by either party to the other, such notice expiring on any day.

4.2 Fixtures and Fittings

All fixtures, fittings, furniture and equipment at any time installed by or on behalf of the Licensee in the Licensed Area and any personal effects or other belongings of the Licensee or of its servants, agents or invitees in the Licensed Area are at all times at the risk of the Licensee and not of the Licensor or the Receiver and the Licensor and the Receiver shall bear no responsibility for any items lost or stolen from the Licensed Area or the Building.

4.3 Licence, not Tenancy

It is hereby agreed that it is not the intention of the Licensor, the Receiver or the Licensee that a tenancy of the Licensed Area shall be created by this Licence.

4.4 Value Added Tax
All sums of whatever nature which are payable by the Licensee under this Licence and which are now or shall at any time after the date of this Licence become subject to Value Added Tax shall be deemed to be exclusive of Value Added Tax and the Licensee shall in addition to such sums pay any Value Added Tax payable or chargeable on them.

4.5 Notices

Any notice under this Licence shall be in writing and shall be sufficiently served if sent to the party upon whom it is intended to serve it by post to the registered office or last known address of that party and shall be assumed to have been delivered in the normal course of post.

4.6 User

Nothing contained in this Licence shall in any way imply or be taken as a warranty by the Licensor or the Receiver that the Licensee may use the Licensed Area for the intended purpose or use provided for in this Licence.

4.7 Separate Agreement

If any of the provisions of this Licence is found by a competent authority to be void or unenforceable, it shall be deemed to be deleted from this Licence and the remaining provisions shall continue to apply.

4.8 Licensee’s Acknowledgement

The Licensee hereby expressly agrees and accepts that the Receiver is acting as agent of the Licensor solely in his capacity as Receiver and enters into this Agreement in that capacity and accordingly no personal liability will attach to the Receiver or his estate, person and/or property TO THE INTENT that any personal liability of the Receiver is hereby excluded.

4.9 Entire Agreement

This Licence constitutes the whole agreement for the use and operation of the Licensed Area by the Licensee and it is expressly declared and agreed that there are no other agreements in relation to such use or operation other than as set out in this Agreement. The Licensee acknowledges that it has not relied upon any oral or written representations made to it by the Licensor, the Receiver or its or his employees or agents.

5 CERTIFICATE

It is hereby certified that this instrument is a release or renunciation of property or of a right or interest in property, which is not a release or renunciation on a sale.

IN WITNESS whereof these presents have been entered into the day and year first herein written.
SCHEDULE 1

Rights Granted to the Licensee

1. The right (in common with all others having the same right) to use those of the common areas in the Building which serve the Licensed Area for the purposes of access to and egress from the Licensed Area subject to and in accordance with such rules and regulations made from time to time governing such access and use.

2. The right to use one (1) car park space in the car park of the Building as allocated for use by the Licensor acting by the Receiver for the purpose only of parking motor vehicles which are the property of the Licensee or its employees provided however that the Licensor acting by the Receiver may alter or vary the location of the parking spaces allocated to the Licensee from time to time.

3. Subject to the Licensee paying and discharging any costs and charges incurred by it relating to the use of meeting rooms located on the Lower Ground Floor of the Building and complying with any rules and regulations relating to their use, the right (in common with all others having the same right) to use the said meeting rooms.

SCHEDULE 2

Rights reserved over the Licensed Area in favour of the Licensor

1. The free and uninterrupted use of all conduits and equipment which are within the Licensed Area and serve other parts of the Building and the right on reasonable prior notice to enter onto the Licensed Area for all purposes associated with inspecting maintaining, repairing, renewing, altering or replacing such conduits and equipment.

2. Full and free right for the Licensor and any person authorised by the Licensor to alter and/or redevelop (by way of improvement renovation refurbishment or otherwise) or carry out modifications or extensions or additions or reductions to or at the Building and/or on neighbouring or nearby premises or to demolish build or rebuild alter or develop the building or buildings on such neighbouring or nearby premises.
PRESENT when the Common Seal of the Licensor was affixed hereto:

/s/ illegible
Receiver for and on behalf of Benton Property Holding Limited (in Receivership)

SIGNED AND DELIVERED by the Receiver:-
in the presence of:

/s/ illegible
Receiver for and on behalf of Benton Property Holding Limited (in Receivership)

Print Name: /s/ Paul Greedon

SIGNED AND DELIVERED by the LICENSEE in the presence of:

/s/ illegible
CONSULTING AGREEMENT

This Consulting Agreement (the “Agreement”) is entered into as of March 18, 2014 and shall become effective as of the Effective Date (as defined below), by and among Horizon Pharma USA, Inc., with its principal place of business at 520 Lake Cook Road, #520, Deerfield, IL 60015 (“Company”), and Virinder Nohria, M.D., Ph.D., an individual residing at 111 Skyline View Road, Franklin, NC 28734 (“Consultant”), for the purpose of setting forth the exclusive terms and conditions by which Company will acquire Consultant’s services on a temporary basis. Company and Consultant may be referred to herein individually as a “Party,” or collectively as the “Parties.”

WHEREAS, Consultant is currently an employee of Vidara Therapeutics Inc. (“Vidara-US”);

WHEREAS, Vidara-US’ parent company, Vidara Therapeutics Holdings LLC, and its affiliated entities, Vidara Therapeutics International LTD, an Irish private limited company (“Vidara”), Hamilton Holdings (USA), Inc., a Delaware corporation and an indirect wholly-owned subsidiary of Vidara (“US HOLDCO”), and Hamilton Merger Sub, Inc., a Delaware corporation and indirect wholly-owned subsidiary of US HOLDCO are entering into a Transaction Agreement and Plan of Merger with the Company (the “Merger Agreement”), pursuant to which the parties thereto will effect a reorganization and merger, among other things (collectively, the “Merger”);

WHEREAS, in order to induce the Parties to enter into the Merger, Consultant agrees to enter into this Agreement; and

WHEREAS, the terms and conditions of this Agreement shall become effective as of the Closing Date of the Merger, as that term is defined in the Merger Agreement (such date of effectiveness, the “Effective Date”). If the Closing (as defined in the Merger Agreement) does not occur, or if the Merger Agreement is terminated in accordance with its terms, this Agreement shall be null and void and have no effect, and shall not be binding on Consultant, Vidara-US, Vidara, the Company, or their respective subsidiaries, parents and affiliated entities (even if executed by the parties).

In consideration of the mutual obligations specified in this Agreement, and any compensation paid to Consultant for his or her services, the Parties agree to the following:

1. Work, Payment and Additional Terms. Attached to this Agreement as EXHIBIT A hereto is a statement of the work performed or to be performed by Consultant, the payment terms for such work, the types of any expenses to be paid in connection with such work, any Background Technology (as defined in Section 3) to be used by Consultant in performing the work, and such other terms and conditions as the Parties deem appropriate or necessary for the performance of the work. Consultant shall perform all such work himself or herself, engaging the assistance of other individuals only with the prior written consent of Company.
2. Nondisclosure and Trade Secrets.

(a) During the term of this Agreement and in the course of Consultant’s performance hereunder, Consultant may receive and otherwise be exposed to confidential and proprietary information owned by Company or received by Company from third parties pursuant to an obligation of confidentiality with respect thereto, relating to Company’s business practices, strategies and technologies. Such confidential and proprietary information may include, but not be limited to, any compound, chemical, peptide, protein, complex, conjugate, virus, extract, media, vector, cell, cell component, cell line, formulation or sample; any procedure, discovery, invention, formula, data, result, idea or technique; any trade secret, trade dress, copyright, patent or other intellectual property right, or any registration or application therefor, or materials relating thereto; and any information relating to any of the foregoing or to any research, development, manufacturing, engineering, marketing, servicing, sales, financing, legal or other business activities or to any present or future products, prices, plans, forecasts, suppliers, clients, customers, employees, consultants or investors; whether in oral, written, graphic or electronic form (collectively referred to as “Information”).

(b) Consultant acknowledges the confidential and secret nature of the Information, and agrees that the Information is the extremely valuable property of Company or of the third party from which Company received such Information. Accordingly, Consultant agrees not to reproduce any of the Information in any format, not to use the Information except in the performance of the work described in this Agreement, and not to disclose all or any part of the Information in any form to any third party, such obligations shall apply in each case during the term of this Agreement and for a period of ten (10) years thereafter, except with the prior written consent of Company. Upon termination of this Agreement for any reason, including expiration of the term of this Agreement, Consultant agrees to cease using and to return to Company all whole and partial copies and derivatives of the Information, whether in Consultant’s possession or under Consultant’s direct or indirect control.

(c) Consultant shall not disclose or otherwise make available to Company in any manner any confidential information of Consultant or any information received by Consultant from third parties, unless Company first agrees in writing to receive such information.


(a) Consultant shall specifically describe and identify in EXHIBIT A to this Agreement any and all technology, including without limitation information, materials and related intellectual property rights, which (i) Consultant intends to use in performing the work under this Agreement, (ii) is either owned solely by Consultant or controlled by Consultant such that Consultant possesses the right to grant a license or sublicense thereunder, and (iii) is in existence prior to the Effective Date (“Background Technology”).

(b) Consultant agrees that any and all ideas, developments, discoveries, improvements, inventions and works of authorship conceived, written, created, tested, or first reduced to practice in the performance of work under this Agreement, including but not limited to any and all ideas, developments, discoveries, improvements, inventions and works of
authorship that are in any way conceived, written, created, improved, tested or first reduced to practice by use of any of Company’s supplies, equipment, facilities, resources, or trade secret information, together with all intellectual property rights relating thereto (“Work Product”) shall be the sole and exclusive property of Company. Consultant hereby assigns and transfers to Company all its right, title and interest in and to any and all such Work Product. If Consultant has any rights to Work Product that cannot, under applicable law, be assigned to Company, Consultant unconditionally and irrevocably waives the enforcement of such rights and all claims and causes of action of any kind against Company with respect to such rights. Consultant agrees, at the Company’s request and expense, to consent to and join in any action to enforce such rights. If Consultant has any right to Work Product that can neither be assigned to Company nor waived by Consultant, Consultant hereby grants to Company an exclusive, irrevocable, perpetual, worldwide, fully paid and royalty free license, with rights to sublicense through multiple levels of sublicensees, to develop, make, have made, use, sell, have sold, offer for sale and import such Work Product. Consultant agrees to maintain written records of all Work Product and to promptly make full written disclosure to Company of all Work Product.

(c) Company acknowledges that Consultant shall retain all of Consultant’s rights in any Background Technology. Consultant hereby grants to Company a non-exclusive, irrevocable, perpetual, worldwide, fully paid and royalty free license, with rights to sublicense through multiple levels of sublicensees, under the Background Technology which was used in connection with, or incorporated into, any of Consultant’s Work Product to develop, make, have made, use, sell, have sold, offer for sale and import Company products, including Work Product.

(d) Consultant further agrees to execute all papers, including without limitation all patent applications, invention assignments and copyright assignments, and otherwise assist Company as reasonably required to perfect Company’s right, title and interest in Work Product as expressly granted to Company under this Agreement. Such assistance shall include but not be limited to providing affidavits or testimony in connection with patent interference, validity or infringement proceedings and participating in other legal proceedings. Consultant’s obligation to assist Company as described above in this paragraph shall continue beyond the termination of this Agreement, provided, however, that following the termination of this Agreement, compensation to Consultant for his time at the rate of $375 per hour, related to such assistance, if required, shall be paid by Company along with reimbursement of any reasonable expenses incurred by Consultant in connection with the provisions of such assistance that would have been eligible for reimbursement if incurred during the term of the Agreement pursuant to the provisions of Exhibit A. If Company is unable, after reasonable effort, to secure Consultant’s signature on any document as provided in this Section 3, Consultant hereby designates and appoints Company and its duly authorized officers and agents as its agent and attorney in fact to execute, verify and file applications, and to do all other lawfully permitted acts necessary to achieve the intent of this Section 3 with the same legal force and effect as if executed by Consultant.

4. Conflicting Engagements. Consultant will notify Company in writing prior to entering into any employment or consulting arrangement with one or more third parties which involves either subject matter substantially similar to services, or which Company might reasonably determine would impair Consultant’s ability to provide the services described in Exhibit A or otherwise fulfill his responsibilities or obligations provided for in this Agreement.
During the term of this Agreement, Consultant shall not accept any employment or consulting work which conflicts with Consultant’s obligations to Company hereunder or which may involve use or disclosure of Information other than as permitted hereunder.

5. Term; Termination. The term of this Agreement shall be for a period beginning on the Effective Date and continuing for twelve (12) months (the “Term”), unless previously terminated pursuant to this Section 5. During the Term, Company may terminate this Agreement if Consultant has failed for a period of thirty (30) days following notice from the Company, to provide the services described in Exhibit A or any other material obligations or responsibilities required pursuant to this Agreement. Consultant may terminate this Agreement if Company, for a period of thirty (30) days following notice from Consultant, is in breach of any of its obligations to Consultant under this Agreement, including, but not limited to any payment or reimbursement obligation. In the event this Agreement is terminated or expires, for whatever reason, Consultant shall cease work immediately after receiving notice from Company, or providing notice to Company, return all Information (including all copies thereof) as provided in Section 2, deliver all Work Product and related documentation to Company, and provide Company with an invoice for any work for which compensation has not already been paid. If compensation has been advanced to Consultant, Consultant shall reimburse any amounts for which work has not been performed prior to the date of the notice of termination. Sections 2, 3, 5, 6, 9, 10, 11, 12, 13, 14, 15, and 16 shall survive the termination of this Agreement for any reason, including expiration of the term of this Agreement.

6. Compliance With Applicable Laws. Consultant warrants that all materials supplied and work performed under this Agreement shall be in compliance with all applicable laws and regulations.

7. Independent Contractor. Consultant is an independent contractor, is not an agent or employee of Company and is not authorized to act on behalf of Company. Consultant will not be eligible for any employee benefits, nor will Company make deductions from any amounts payable to Consultant for taxes or social securities. Payment of all taxes and social securities due on any amounts paid to Consultant hereunder shall be the sole responsibility of Consultant.

8. Assignment. The Parties’ rights and obligations under this Agreement will bind and inure to the benefit of their respective successors and assigns, except that Consultant may not delegate or assign any of his or her obligations or rights under this Agreement without Company’s prior written consent.

9. Complete Agreement. This Agreement and EXHIBIT A attached hereto and hereby incorporated herein, constitute the Parties’ final, exclusive and complete understanding and agreement with respect to the subject matter hereof, and supersede all prior and contemporaneous understandings and agreements relating to its subject matter.

10. Waiver; Amendment; Severability. This Agreement may not be waived, modified or amended unless mutually agreed upon in writing by both Parties. In the event any provision of this Agreement is found to be legally unenforceable, such unenforceability shall not prevent enforcement of any other provision of the Agreement.
11. **Choice of Law.** This Agreement shall be governed by the laws of the State of Illinois, without regard to any conflicts of law principals thereof that would call for the application of the laws of any other jurisdiction. The Parties consent to the exclusive jurisdiction and venue of the federal court in the Northern District of Illinois, and state courts located in the state of Illinois, county of Cook. Nothing in this Section 12 limits the rights of the Parties to seek appeal of a decision of a Illinois court outside of Illinois that has proper jurisdiction over the decision of a court sitting in Illinois.

12. **Notice.** For the purposes of this Agreement, notices, demands, and all other forms of communication provided for in this Agreement shall be in writing and shall be deemed to have been duly given when delivered or (unless otherwise specified) mailed by registered mail, return receipt requested, postage prepaid, or by confirmed facsimile, addressed as set forth below, or to such other address as any party may have furnished to the other in writing in accordance herewith, except that notices of address shall be effective only upon receipt, as follows:

**If to Company:**

Horizon Pharma USA, Inc.
520 Lake Cook Road, #520
Deerfield, IL 60015
Attention: Timothy P. Walbert, Chairman, President and CEO
Fax: 224-383-3001

**If to the Consultant:**

Virinder Nohria, M.D., Ph.D.
111 Skyline View Road
Franklin, NC 28734

Any such written notice shall be deemed given on the earlier of the date on which such notice is personally delivered, sent by telefax with a confirmatory copy sent by privileged mail, or upon confirmation of receipt in case of registered mail. Either party may change its address for notices by giving written notice to the other party in the manner specified in this section.

13. **Execution in Facsimile and Electronic Signatures.** Facsimile and electronically transmitted signatures shall have the same force and effect as original signatures.

14. **Execution in Counterparts.** This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which together shall constitute a single instrument.

15. **Legal And Equitable Remedies.** Consultant hereby acknowledges and agrees that in the event of any breach of this Agreement by Consultant, including, without limitation, the actual or threatened disclosure of Information without the prior express written consent of Company, Company will suffer an irreparable injury, such that no remedy at law will afford it adequate protection against, or appropriate compensation for, such injury. Accordingly, Consultant agrees that Company shall have the right to enforce this Agreement and any of its
provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that Company may have for a breach of this Agreement.

16. Warranty; Indemnification. Consultant warrants that he or she has good and marketable title to all Work Product. Consultant further warrants that the Work Product shall be free and clear of all liens, claims, encumbrances or demands of third parties, including any claims by any such third parties with respect to such third parties’ intellectual property rights in the Work Product. Consultant warrants that Consultant has not been debarred under any applicable law, rule or regulation including, without limitation, Section 306(a) or 306(b) of the Federal Food, Drug and Cosmetic Act (codified at 21 U.S.C. 335(a) and 335(b)). Consultant covenants that should Consultant be convicted in the future of any act for which a person can be debarred as described in any applicable law, rule or regulation including, without limitation, Section 306(a) or 306(b) of the Federal Food, Drug and Cosmetic Act, Consultant shall immediately notify Company of such conviction in writing. Consultant shall indemnify, defend and hold harmless Company and its officers, agents, directors, employees, and customers from and against any claim, liability, loss, judgment or expense (including reasonable attorneys’ and expert witnesses’ fees and costs) resulting from or arising out of any such claims by any third parties which are based upon or are the result of any breach of such warranties. Should Company permit Consultant to use any of Company’s equipment, tools or facilities (the “Company Equipment”) in the performance of the services during the term of this Agreement, such permission will be gratuitous and Consultant shall indemnify, defend and hold harmless Company and its officers, directors, agents and employees from and against any claim, loss, expense or judgment of injury to person or property (including death) arising out of Consultant’s willful misconduct or negligent use of any such Company Equipment.

IN WITNESS WHEREFORE, the Parties have signed this Agreement on the date first written above.

HORIZON PHARMA USA, INC.

Timothy P. Walbert  
Chairman, President and Chief Executive Officer

Signature:  /s/ Timothy P. Walbert

CONSULTANT:

Virinder Nohria, M.D., Ph.D.

Signature:  /s/ Virinder Nohria, M.D., Ph.D.
EXHIBIT A

Work to be performed: Work is related to ongoing clinical, regulatory and business support of ACTIMMUNE. Consultant shall be available at least as needed and requested by Company during the term of this Agreement. In the event, that the Consultant is asked to work more than five days in any month, the Company agrees to pay the Consultant for his time worked in excess of such five days at the rate of $375 per hour. Consultant’s work shall be performed from Consultant’s offices in Franklin, North Carolina unless Company has a specific need for Consultant, on specific limited occasion, to provide his services at a different location. Consultant shall be available to attend, either in person or via conference call, live meetings during regular business hours, as reasonably requested by Company; provided Company shall use reasonable efforts to provide Consultant with advance notice of at least three (3) business day; further provided that Consultant shall use reasonable efforts to be available on shorter notice if practicable.

Type or rate of payment: Payment for work performed during any Term will be paid monthly, as described below, in one single payment equal to ten thousand dollars ($10,000.00) for each month when work is rendered during the Term.

If Consultant is requested to provide services at any location other than his Franklin, North Carolina office, Consultant shall be reimbursed for reasonable travel expenses actually incurred, including air and ground transportation, standard lodging and meals, up to an amount pre-approved by Company in accordance with Company’s existing policies, upon submission and verification of customary receipts and vouchers and such reimbursement shall be made within thirty days of the submission of such receipts and vouchers but in no event later than the last day of the calendar year following the calendar year in which the Consultant incurred the reimbursable expense. All air and ground transportation shall be coach class. Consultant shall use reasonable efforts to book transportation at least twenty-one (21) days in advance of the date of expected travel. For meals, Company shall reimburse Consultant for reasonable expenses. Any amount of expenses eligible for reimbursement during a calendar year shall not affect the expenses eligibility for reimbursement during any other calendar year. The right to reimbursement pursuant to this Agreement shall not be subject to liquidation or exchange for any other benefit.

Timing of payment(s): Payments during the Term shall be due on or the before the 15th day of the month following the month for which the work has been performed, unless this Agreement is sooner terminated pursuant to the terms of Section 5 hereof.
This Executive Employment Agreement (hereinafter referred to as the “Agreement”), is entered into by and between Horizon Pharma, Inc., a Delaware corporation, and its wholly owned subsidiary, Horizon Pharma USA, Inc., a Delaware corporation, each having a principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, IL 60015, (hereinafter referred to together as the “Company”) and Barry Moze (hereinafter referred to as the “Executive”). The terms of this Agreement shall be effective commencing September 18, 2014 (the “Effective Date”).

REcITAlS

WHEREAS, the Company desires assurance of the continued association and services of the Executive in order to continue to retain the Executive’s experience, skills, abilities, background and knowledge, and is willing to continue to engage the Executive’s services on the terms and conditions set forth in this Agreement; and

WHEREAS, Executive desires to be in the continued employ of the Company, and is willing to accept such continued employment on the terms and conditions set forth in this Agreement.

AGREEmENT

1. Employment.

1.1 Term. The Company hereby agrees to continue to employ the Executive, and the Executive hereby accepts continued employment by the Company, upon the terms and conditions set forth in this Agreement. The Executive’s original date of hire was May 19, 2014. Executive’s employment shall be governed under the terms set forth in this Agreement beginning on the Effective Date and shall continue until it is terminated pursuant to Section 4 herein (hereinafter referred to as the “Term”).

1.2 Title. The Executive shall continue to have the title of Executive Vice President, Corporate Development of the Company (such position held by Executive during such period is hereinafter referred to as “EVP CD”) and Executive shall continue to serve in such other capacity or capacities commensurate with his position as EVP CD as the President and CEO of the Company may from time to time prescribe.

1.3 Duties. The Executive shall do and perform all services, acts or things necessary or advisable to manage and conduct the business of the Company and shall have the authority and responsibilities which are generally associated with the position of EVP CD including being responsible for the Company’s corporate strategy, human resources, information technology, project management, business operations and government affairs. The Executive shall report to the President and CEO.
1.4 Policies and Practices. The employment relationship between the Parties shall be governed by this Agreement and the policies and practices established by the Company and the Board of Directors (hereinafter referred to as the “Board”). In the event that the terms of this Agreement differ from or are in conflict with the Company’s policies or practices or the Company’s Employee Handbook, this Agreement shall control.

1.5 Location. The Executive shall perform the services the Executive is required to perform pursuant to this Agreement in the headquarters office for the Company in the Deerfield, Illinois area. The Company may from time to time require the Executive to travel temporarily to other locations outside of the Deerfield, Illinois area in connection with the Company’s business.

2. Loyalty of Executive.

2.1 Loyalty. During the Executive’s employment by the Company, the Executive shall devote the Executive’s business energies, interest, abilities and productive time to the proper and efficient performance of Executive’s duties under this Agreement. Subject to the prior written consent of the President and CEO, the Executive is permitted to serve on the board of directors of one other company, so long as the other company does not compete with the Company.

2.2 Exclusive Employment. Except with the prior written consent of the Chief Executive Officer, Executive shall not, during the term of this Agreement, undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor. Executive may engage in any civic and not-for-profit activities so long as such activities do not materially interfere with the performance of his duties hereunder or present a conflict of interest with the Company.

2.3 Agreement not to Participate in Company’s Competitors. During the Term of this Agreement, the Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known by Executive to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise or in any company, person or entity that is, directly or indirectly, in competition with the business of the Company or any of its affiliates. Notwithstanding the foregoing, Executive may invest and/or maintain investments in any public or private entity up to an amount of 2% of an entity’s fully diluted shares and on a passive basis.

3. Compensation to Executive.

3.1 Base Salary. The Company shall pay the Executive a base salary at the initial annualized rate of four hundred twenty seven thousand dollars ($427,000.00) per year, subject to standard deductions and withholdings, or such higher rate as may be determined from time to time by the Board or the compensation committee thereof (hereinafter referred to as the “Base Salary”). Such Base Salary shall be paid in accordance with the Company’s standard payroll practice. Payments of salary installments shall be made no less frequently than once per month. Executive’s Base
Salary will be reviewed annually each December and Executive shall be eligible to receive a salary increase (but not decrease) annually in an amount to be determined by the Board or the compensation committee thereof in its sole and exclusive discretion. Once increased, the new salary shall become the Base Salary for purposes of this Agreement and shall not be reduced without the Executive’s written consent. Any material reduction in the Base Salary of the Executive, without his written consent, may be deemed Good Reason as set forth in and subject to Section 4.5.2 of this Agreement.

3.2 Discretionary Bonus. Provided the Executive meets the conditions stated in this Section 3.2, the Executive shall be eligible for an annual discretionary bonus (hereinafter referred to as the “Bonus”) with a target amount of fifty percent (50%) of the Executive’s Base Salary, subject to standard deductions and withholdings, based on the Board’s determination, in good faith, and based upon the Executive’s individual achievement and company performance objectives as set by the Board or the compensation committee thereof, of whether the Executive has met such performance milestones as are established for the Executive by the Board or the compensation committee thereof, in good faith, in consultation with the Executive (hereinafter referred to as the “Performance Milestones”). The Performance Milestones will be based on certain factors including, but not limited to, the Executive’s performance and the Company’s financial performance. The Executive’s Bonus target will be reviewed annually and may be adjusted by the Board or the compensation committee thereof in its discretion, provided however, that the Bonus target may only be materially reduced upon Executive’s written consent. The Executive must be employed on the date the Bonus is awarded to be eligible for the Bonus, subject to the termination provisions thereof. The Bonus shall be paid during the calendar year following the performance calendar year.

3.3 Equity Awards. All Company equity awards previously granted to Executive shall continue in effect from and following the Effective Date in accordance with their existing terms. Executive may be eligible to receive additional grants of Company equity awards in the sole discretion and subject to the approval of the Board.

3.4 Legal Review. Upon the Executive’s submission of appropriate itemized proof and verification of reasonable and customary legal fees incurred by the Executive in obtaining legal advice associated with the review, preparation, approval, and execution of this Agreement, the Company shall pay for up to $10,000.00 of such legal fees subject to receipt of appropriate proof and verification of such legal fees no later than sixty (60) days of receipt of an invoice for legal services from the Executive and/or his attorneys. To be eligible for reimbursement, the invoice must be submitted no later than ninety (90) days after the legal fees are incurred.

3.5 Changes to Compensation. The Executive’s compensation may be changed from time to time by mutual agreement of the Executive and the Company. In the event that the Executive’s base salary is materially decreased without his written consent, said decrease will be Good Reason for the Executive to terminate the Agreement as set forth in and subject to Section 4.5.2 of this Agreement.
3.6 Taxes. All amounts paid under this Agreement to the Executive by the Company will be paid less applicable tax withholdings and any other withholdings required by law or authorized by the Executive.

3.7 Benefits. The Executive shall, in accordance with Company policy and the terms of the applicable plan documents, be eligible to participate in benefits under any executive benefit plan or arrangement which may be in effect from time to time and made available to the Company’s executives or key management employees, provided, however, that the Executive shall be entitled to at least four (4) weeks of paid vacation annually.

3.8 Vidara Transaction Section 4985 Gross-Up. To the extent that the Company agrees to reimburse any of the executive officers of the Company for any excise tax imposed upon them pursuant to Section 4985 of the Code in connection with the Company’s strategic transaction with Vidara Therapeutics International Ltd. that closed on September 19, 2014, including any reimbursement for income taxes imposed upon such excise tax reimbursement, the Executive shall be entitled to be reimbursed on the same basis as the other executive officers.

4. Termination.

4.1 Termination by the Company. The Executive’s employment with the Company may be terminated only under the following conditions:

4.1.1 Termination for Death or Disability. The Executive’s employment with the Company shall terminate effective upon the date of the Executive’s death or “Complete Disability” (as defined in Section 4.5.1), provided, however, that this Section 4.1.1 shall in no way limit the Company’s obligations to provide such reasonable accommodations to the Executive and/or his heirs as may be required by law.

4.1.2 Termination by the Company For Cause. The Company may terminate the Executive’s employment under this Agreement for “Cause” (as defined in Section 4.5.3) by delivery of written notice to the Executive specifying the Cause or Causes relied upon for such termination, provided that such notice is delivered within two (2) months following the occurrence or discovery of any event or events constituting “Cause”. Any notice of termination given pursuant to this Section 4.1.2 shall effect termination as of the date of the notice or such date as specified in the notice. The Executive shall have the right to appear before the CEO before any termination for Cause becomes effective and binding upon the Executive.

4.1.3 Termination by the Company Without Cause. The Company may terminate the Executive’s employment under this Agreement at any time and for any reason or no reason subject to the requirements set out in Section 4.4 of this Agreement. Such termination shall be effective on the date the Executive is so informed or as otherwise specified by the Company, pursuant to notice requirements set forth in Section 6 of this Agreement.
4.2 Termination By The Executive. The Executive may terminate his employment with the Company at any time and for any reason or no reason, including, but not limited, to the following conditions:

4.2.1 Good Reason. The Executive may terminate his employment under this Agreement for “Good Reason” (as defined below in Section 4.5.2) by delivery of written notice to the Company specifying the Good Reason relied upon by the Executive for such termination in accordance with the requirements of such section.

4.2.2 Without Good Reason. The Executive may terminate the Executive’s employment hereunder for other than Good Reason upon thirty (30) days written notice to the Company.

4.3 Termination by Mutual Agreement of the Parties. The Executive’s employment pursuant to this Agreement may be terminated at any time upon a mutual agreement in writing of the Parties. Any such termination of employment shall have the consequences specified in such mutual agreement.

4.4 Compensation to Executive Upon Termination. In connection with any termination of the Executive’s employment for any reason, the Executive or the Executive’s estate, as applicable, shall be entitled to any amounts payable to the Executive or the Executive’s beneficiaries subject to and accordance with the terms of the Company’s employee welfare benefit plans or policies (excluding any severance pay).

4.4.1 Death or Complete Disability. If the Executive’s employment shall be terminated by death or Complete Disability as provided in Section 4.1.1, the Company shall pay to Executive, and/or Executive’s heirs, all earned but unpaid Base Salary, any earned but unpaid discretionary bonuses for any prior period at such time as bonuses would have been paid if the Executive remained employed, all accrued but unpaid business expenses, and all accrued but unused vacation time earned through the date of termination at the rate in effect at the time of termination (hereinafter referred to as the “Accrued Amounts”), less standard deductions and withholdings. The Executive shall also be eligible to receive a pro-rata bonus for the year of termination, as determined by the Board or the Compensation Committee of the Board based on actual performance and the period of the year he was employed (hereinafter referred to as the “Pro-rata Bonus”), less standard deductions and withholdings, to be paid as a lump sum within thirty (30) days after the date of termination.

4.4.2 With Cause or Without Good Reason. If the Executive’s employment shall be terminated by the Company for Cause, or if the Executive terminates employment hereunder without Good Reason, the Company shall pay the Executive’s Base Salary, accrued but unpaid business expenses and accrued and unused vacation benefits earned through the date of termination at the rate in effect at the time of termination, less standard deductions and withholdings.
4.4.3 Without Cause or For Good Reason.

(i) Not in Connection With a Change in Control. If the Company terminates the Executive’s employment without Cause or the Executive terminates his employment for Good Reason, and Section 4.4.3(ii) below does not apply, the Company shall pay the Accrued Amounts subject to standard deductions and withholdings, to be paid as a lump sum no later than thirty (30) days after the date of termination. In addition, subject to the limitations stated in this Agreement and upon the Executive’s furnishing to the Company an executed waiver and release of claims (the form of which is attached hereto as Exhibit A) (the “Release”) within the applicable time period set forth therein, but in no event later than forty-five days following termination of employment and permitting such Release to become effective in accordance with its terms (the “Release Effective Date”), and subject to Executive entering into no later than the Release Effective Date a non-competition agreement to be effective during the Severance Period (as defined below), substantially similar to Section 2.3, and continuing to abide by its terms during the Severance Period, the Executive shall be entitled to:

(a) the equivalent of the Executive’s Base Salary in effect at the time of termination will continue to be paid for a period of twelve (12) months following the date of termination (hereinafter referred to as the “Severance Period”), less standard deductions and withholdings, to be paid during the Severance Period according to the Company’s regular payroll practices, subject to any delay in payment required by Section 4.6 in connection with the Release Effective Date; and

(b) in the event the Executive timely elects continued coverage under COBRA, the Company will continue to pay the same portion of Executive’s COBRA health insurance premium as the percentage of health insurance premiums that it paid during the Executive’s employment, including any amounts that Company paid for benefits to the qualifying family members of the Executive, following the date of termination up until the earlier of either (i) the last day of the Severance Period or, (ii) the date on which the Executive begins full-time employment with another company or business entity which offers comparable health insurance coverage to the Executive (such period, the “COBRA Payment Period”). Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Executive a taxable cash amount, which payment shall be made regardless of whether the Executive or his qualifying family members elect COBRA continuation coverage (the “Health Care Benefit Payment”). The Health Care Benefit Payment shall be paid in monthly or bi-weekly installments on the same schedule that the COBRA premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company otherwise would have paid for COBRA insurance premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the COBRA Payment Period.

(ii) In Connection With a Change in Control. If the Company (or its successor) terminates the Executive’s employment without Cause or the Executive terminates his employment for Good Reason within the period commencing
ninety (90) days immediately prior to a Change in Control of the Company and ending eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the Executive shall receive the Accrued Amounts subject to standard deductions and withholdings, to be paid as a lump sum no later than thirty (30) days after the date of termination. In addition, subject to the limitations stated in this Agreement and upon the Executive’s furnishing to the Company (or its successor) an executed Release within the applicable time period set forth therein, but in no event later than forty-five days following termination of employment and permitting such Release to become effective in accordance with its terms, and subject to Executive entering into no later than the Release Effective Date a non-competition agreement to be effective during the Severance Period, substantially similar to Section 2.3, and continuing to abide by its terms during the Severance Period, then in lieu of (and not additional to) the benefits provided pursuant to Section 4.4.3(i) above, the Executive shall be entitled to:

(a) the equivalent of the Executive’s Base Salary in effect at the time of termination will continue to be paid during the Severance Period, less standard deductions and withholdings, to be paid during the Severance Period according to the Company’s regular payroll practices, subject to any delay in payment required by Section 4.6 in connection with the Release Effective Date;

(b) Executive’s target Bonus in effect at the time of termination, or if none, the last target Bonus in effect for Executive, less standard deductions and withholdings, to be paid in a lump sum within ten (10) days following the later of (i) the Release Effective Date, or (ii) the effective date of the Change in Control; and

(c) in the event the Executive timely elects continued coverage under COBRA, the Company will continue to pay the same portion of Executive’s COBRA health insurance premium as the percentage of health insurance premiums that it paid during the Executive’s employment, including any amounts that Company paid for benefits to the qualifying family members of the Executive, following the date of termination until the expiration of the COBRA Payment Period. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Executive the Health Care Benefit Payment, which payment shall be made regardless of whether the Executive or his qualifying family members elect COBRA continuation coverage. The Health Care Benefit Payment shall be paid in monthly or bi-weekly installments on the same schedule that the COBRA premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company otherwise would have paid for COBRA insurance premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the COBRA Payment Period.

(iii) No Duplication of Benefits. For the avoidance of doubt, in no event will Executive be entitled to benefits under Section 4.4.3(i) and Section
4.4.3(ii). If Executive commences to receive benefits under Section 4.4.3(i) due to a qualifying termination prior to a Change in Control and thereafter becomes entitled to benefits under Section 4.4.3(ii), any benefits previously provided to Executive under Section 4.4.3(i) shall offset the benefits to be provided to Executive under Section 4.4.3(ii) and shall be deemed to have been provided to Executive pursuant to Section 4.4.3(ii).

4.4.4 Equity Award Acceleration.

(i) In Connection With a Change in Control. In the event that the Executive’s employment is terminated without Cause or for Good Reason within the ninety (90) days immediately preceding or during the eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the vesting of any Company equity awards granted to Executive shall be fully accelerated such that on the effective date of such termination (or, if later, the date of the Change in Control) one hundred percent (100%) of the equity award shares granted to Executive prior to such termination shall be fully vested and immediately exercisable, if applicable, by the Executive.

(ii) Release and Waiver. Any equity vesting acceleration pursuant to this Section 4.4.4 shall be conditioned upon and subject to the Executive’s delivery to the Company of a fully effective Release in accordance with the terms specified by Section 4.4.3 hereof and such vesting acceleration benefit shall be in addition to the benefits provided by Section 4.4.3 hereof.

4.5 Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

4.5.1 Complete Disability. “Complete Disability” shall mean the inability of the Executive to perform the Executive’s duties under this Agreement, whether with or without reasonable accommodation, because the Executive has become permanently disabled within the meaning of any policy of disability income insurance covering employees of the Company then in force. In the event the Company has no policy of disability income insurance covering employees of the Company in force when the Executive becomes disabled, the term “Complete Disability” shall mean the inability of the Executive to perform the Executive’s duties under this Agreement, whether with or without reasonable accommodation, by reason of any incapacity, physical or mental, which the Board, based upon medical advice or an opinion provided by a licensed physician, determines to have incapacitated the Executive from satisfactorily performing all of the Executive’s usual services for the Company, with or without reasonable accommodation, for a period of at least one hundred eighty (180) days during any twelve (12) month period that need not be consecutive.
4.5.2 Good Reason. “Good Reason” for the Executive to terminate the Executive’s employment hereunder shall mean the occurrence of any of the following events without the Executive’s consent:

(i) a material reduction in the Executive’s duties, authority, or responsibilities relative to the duties, authority, or responsibilities in effect immediately prior to such reduction, including by way of example, having the same title, duties, authority and responsibilities at a subsidiary level following a Change in Control;

(ii) the relocation of the Executive’s primary work location to a point more than fifty (50) miles from the Executive’s current work location set forth in Section 1.5 that requires a material increase in Executive’s one-way driving distance;

(iii) a material reduction by the Company of the Executive’s base salary or annual target Bonus opportunity, without the written consent of the Executive, as initially set forth herein or as the same may be increased from time to time pursuant to this Agreement; and

(iv) a material breach by the Company of Section 1.2 of this Agreement.

Provided, however that, such termination by the Executive shall only be deemed for Good Reason pursuant to the foregoing definition if (i) the Company is given written notice from the Executive within sixty (60) days following the first occurrence of the condition that he considers to constitute Good Reason describing the condition and the Company fails to satisfactorily remedy such condition within thirty (30) days following such written notice, and (ii) the Executive terminates employment within thirty (30) days following the end of the period within which the Company was entitled to remedy the condition constituting Good Reason but failed to do so.

4.5.3 Cause. “Cause” for the Company to terminate Executive’s employment hereunder shall mean the occurrence of any of the following events, as determined reasonably and in good faith by the Board or a committee designated by the Board:

(i) the Executive’s gross negligence or willful failure to substantially perform his duties and responsibilities to the Company or willful and deliberate violation of a Company policy;

(ii) the Executive’s conviction of a felony or the Executive’s commission of any act of fraud, embezzlement or dishonesty against the Company or involving moral turpitude that is likely to inflict or has inflicted material injury on the business of the Company, to be determined by the sole discretion of the Company;

(iii) the Executive’s unauthorized use or disclosure of any proprietary information or trade secrets of the Company or any other party that the Executive owes an obligation of nondisclosure as a result of the Executive’s relationship with the Company; and

(iv) the Executive’s willful and deliberate breach of the obligations under this Agreement that causes material injury to the business of the Company.
4.5.4 Change in Control. For purposes of this Agreement, “Change in Control” means: (i) a sale of all or substantially all of the assets of the Company; (ii) a merger or consolidation in which the Company is not the surviving entity and in which the holders of the Company’s outstanding voting stock immediately prior to such transaction own, immediately after such transaction, securities representing less than fifty percent (50%) of the voting power of the entity surviving such transaction or, where the surviving entity is a wholly-owned subsidiary of another entity, the surviving entity’s parent; (iii) a reverse merger in which the Company is the surviving entity but the shares of Common Stock outstanding immediately preceding the merger are converted by virtue of the merger into other property, whether in the form of securities of the surviving entity’s parent, cash or otherwise, and in which the holders of the Company’s outstanding voting stock immediately prior to such transaction own, immediately after such transaction, securities representing less than fifty percent (50%) of the voting power of the Company or, where the Company is a wholly-owned subsidiary of another entity, the Company’s parent; or (iv) an acquisition by any person, entity or group (excluding any employee benefit plan, or related trust, sponsored or maintained by the Company or subsidiary of the Company or other entity controlled by the Company) of the beneficial ownership of securities of the Company representing at least seventy-five percent (75%) of the combined voting power entitled to vote in the election of Directors; provided, however, that nothing in this paragraph shall apply to a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company.

4.6 Application of Internal Revenue Code Section 409A. Notwithstanding anything to the contrary set forth herein, any payments and benefits provided under this Agreement (the “Severance Benefits”) that constitute “deferred compensation” within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the “Code”) and the regulations and other guidance thereunder and any state law of similar effect (collectively “Section 409A”) shall not commence in connection with Executive’s termination of employment unless and until Executive has also incurred a “separation from service” (as such term is defined in Treasury Regulation Section 1.409A-1(h) (“Separation From Service”), unless the Company reasonably determines that such amounts may be provided to Executive without causing Executive to incur the additional 20% tax under Section 409A.

It is intended that each installment of the Severance Benefits payments provided for in this Agreement is a separate “payment” for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that payments of the Severance Benefits set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulation Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if the Company (or, if applicable, the successor entity thereto) determines that the Severance Benefits constitute “deferred compensation” under Section 409A and Executive is, on the termination of service, a “specified employee” of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Severance Benefit payments shall be delayed until
the earlier to occur of: (i) the date that is six months and one day after Executive’s Separation From Service, or (ii) the date of Executive’s death (such applicable date, the “Specified Employee Initial Payment Date”), the Company (or the successor entity thereto, as applicable) shall (A) pay to Executive a lump sum amount equal to the sum of the Severance Benefit payments that Executive would otherwise have received through the Specified Employee Initial Payment Date if the commencement of the payment of the Severance Benefits had not been so delayed pursuant to this Section and (B) commence paying the balance of the Severance Benefits in accordance with the applicable payment schedules set forth in this Agreement.

Notwithstanding anything to the contrary set forth herein, Executive shall receive the Severance Benefits described above, if and only if Executive duly executes and returns to the Company within the applicable time period set forth therein, but in no event more than forty-five days following Separation From Service, the Company’s standard form of release of claims in favor of the Company (attached to this Agreement as Exhibit A) (the “Release”) and permits the release of claims contained therein to become effective in accordance with its terms (such latest permitted date, the “Release Deadline”). If the severance benefits are not covered by one or more exemptions from the application of Section 409A and the Release could become effective in the calendar year following the calendar year in which Executive separates from service, the Release will not be deemed effective any earlier than the Release Deadline. Notwithstanding any other payment schedule set forth in this Agreement, none of the Severance Benefits will be paid or otherwise delivered prior to the effective date (or deemed effective date) of the Release. Except to the extent that payments may be delayed until the Specified Employee Initial Payment Date pursuant to the preceding paragraph, on the first regular payroll pay day following the effective date of the Release, the Company will pay Executive the Severance Benefits Executive would otherwise have received under the Agreement on or prior to such date but for the delay in payment related to the effectiveness of the Release, with the balance of the Severance Benefits being paid as originally scheduled.

The severance benefits are intended to qualify for an exemption from application of Section 409A or comply with its requirements to the extent necessary to avoid adverse personal tax consequences under Section 409A, and any ambiguities herein shall be interpreted accordingly.

4.7 Application of Internal Revenue Code Section 280G. If any payment or benefit Executive would receive pursuant to a Change in Control from the Company or otherwise (“Payment”) would (i) constitute a “parachute payment” within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then such Payment shall be equal to the Reduced Amount. The “Reduced Amount” shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive’s receipt, on an after-tax basis, of the
greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting “parachute payments” is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, Executive agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, Executive will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

Unless Executive and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

The Company shall use commercially reasonable efforts to cause the accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Executive and the Company within fifteen (15) calendar days after the date on which Executive’s right to a Payment is triggered (if requested at that time by Executive or the Company) or such other time as requested by Executive or the Company.

4.8 Indemnification Agreement. The Company and the Executive have previously entered into an indemnification agreement which shall continue to govern the terms of Executive’s employment following the Effective Date, and a copy of which is attached hereto as Exhibit B.

4.9 Confidential Information and Invention Assignment Agreement. The Executive has previously executed the Company’s Confidential Information and Invention Assignment Agreement the terms of which shall continue to govern the terms of Executive’s employment following the Effective Date, and a copy of which is attached as Exhibit C.

4.10 No Mitigation or Offset. The Executive shall not be required to seek or accept other employment, or otherwise to mitigate damages, as a condition to receipt of the Severance Benefits, and the Severance Benefits shall not be offset by any amounts received by the Executive from any other source, except to the extent that the Executive’s right the benefits described in Sections 4.4.3(i)(b) or 4.4.3(ii)(c), as applicable, are terminated by reason of the Executive obtaining full-time employment with another company or business entity which offers comparable health insurance coverage.
5. Assignment and Binding Effect.

This Agreement shall be binding upon the Executive and the Company and inure to the benefit of the Executive and the Executive’s heirs, executors, personal representatives, assigns, administrators and legal representatives. Because of the unique and personal nature of the Executive’s duties under this Agreement, neither this Agreement nor obligations under this Agreement shall be assignable by the Executive. This Agreement shall be binding upon and inure to the benefit of the Company and its successors, assigns and legal representatives, provided that the Agreement may only be assigned to an acquirer of all or substantially all of the Company’s assets. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, “successor” means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company.


For the purposes of this Agreement, notices, demands, and all other forms of communication provided for in this Agreement shall be in writing and shall be deemed to have been duly given when delivered or (unless otherwise specified) mailed by registered mail, return receipt requested, postage prepaid, or by confirmed facsimile, addressed as set forth below, or to such other address as any party may have furnished to the other in writing in accordance herewith, except that notices of address shall be effective only upon receipt, as follows:

If to the Company:
Horizon Pharma, Inc.
520 Lake Cook Road, Suite 520
Deerfield, IL 60015
Attention: Timothy P. Walbert, Chairman, President & CEO
Fax: 847-572-1372

If to the Executive:
Barry Moze
6160 South Elm
Burr Ridge, IL 60527

Any such written notice shall be deemed given on the earlier of the date on which such notice is personally delivered or five (5) days after its deposit in the United States mail as specified above. Either Party may change its address for notices by giving written notice to the other Party in the manner specified in this section.
7. **Choice of Law.**

This Agreement shall be governed by the laws of the State of Illinois, without regard to any conflicts of law principals thereof that would call for the application of the laws of any other jurisdiction. The Parties consent to the exclusive jurisdiction and venue of the federal court in the Northern District of Illinois, and state courts located in the state of Illinois, county of Cook. Nothing in this Section 7 limits the rights of the Parties to seek appeal of a decision of an Illinois court outside of Illinois that has proper jurisdiction over the decision of a court sitting in Illinois.

8. **Integration.**

This Agreement, including Exhibit A, Exhibit B, Exhibit C, contains the complete, final and exclusive agreement of the Parties relating to the terms and conditions of the Executive’s employment and the termination of Executive’s employment, and supersedes all prior and contemporaneous oral and written employment agreements or arrangements between the Parties.

9. **Amendment.**

This Agreement cannot be amended or modified except by a written agreement signed by the Executive and the Company.

10. **Waiver.**

No term, covenant or condition of this Agreement or any breach thereof shall be deemed waived, except with the written consent of the Party against whom the waiver is claimed, and any waiver or any such term, covenant, condition or breach shall not be deemed to be a waiver of any preceding or succeeding breach of the same or any other term, covenant, condition or breach.

11. **Severability.**

The finding by a court of competent jurisdiction of the unenforceability, invalidity or illegality of any provision of this Agreement shall not render any other provision of this Agreement unenforceable, invalid or illegal. Such court shall have the authority to modify or replace the invalid or unenforceable term or provision with a valid and enforceable term or provision, which most accurately represents the Parties’ intention with respect to the invalid, unenforceable, or illegal term or provision.

12. **Interpretation; Construction.**

The headings set forth in this Agreement are for convenience of reference only and shall not be used in interpreting this Agreement. This Agreement has been drafted and negotiated by legal counsel representing the Company and the Executive. The Parties acknowledge that each Party and its counsel has reviewed and revised, or had an opportunity to review and revise, this Agreement, and any rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Agreement.
13. **Execution by Facsimile Signatures and in Counterparts.**

The parties agree that facsimile signatures shall have the same force and effect as original signatures. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

14. **Survival.**

The provisions of this Agreement, and of all other agreements referenced herein, shall survive the termination of this Agreement, and of the Executive’s employment by the Company for any reason, to the extent necessary to enable the parties to enforce their respective rights hereunder.

[Remainder of Page Intentionally Left Blank]
IN WITNESS WHEREFORE, the parties have signed this Agreement on the date first written above.

COMPANY:

HORIZON PHARMA, INC.
HORIZON PHARMA USA, INC.

By:

Title: Chairman, President & CEO

Print Name: Timothy P. Walbert

/s/ Timothy P. Walbert
Signature:

As authorized agent of the Company

February 25, 2015
Date

EXECUTIVE:

Barry Moze

/s/ Barry Moze
Barry Moze, individually

February 25, 2015
Date
RELEASE AND WAIVER OF CLAIMS

In consideration of the payments and other benefits set forth in Section 4.4 of the Executive Employment Agreement dated __________ ____ (the “Employment Agreement”), to which this form is attached, I, Barry Moze, hereby furnish Horizon Pharma, Inc. and Horizon Pharma USA, Inc. (together the “Company”), with the following release and waiver (“Release and Waiver”).

In exchange for the consideration provided to me by the Employment Agreement that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, Affiliates, and assigns from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring relating to my employment or the termination thereof prior to my signing this Release and Waiver. This general release includes, but is not limited to: (1) all claims arising out of or in any way related to my employment with the Company or the termination of that employment; (2) all claims related to my compensation or benefits from the Company, including, but not limited to, salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership interests in the Company; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (4) all tort claims, including, but not limited to, claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims, including, but not limited to, claims for discrimination, harassment, retaliation, attorneys’ fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) (“ADEA”), the Illinois Human Rights Act, the Illinois Equal Pay Act, the Illinois Religious Freedom Restoration Act, and the Illinois Genetic Information Privacy Act. Notwithstanding the foregoing, this Release and Waiver, shall not release or waive my rights: to indemnification under the articles and bylaws of the Company or applicable law; to payments under Sections __________ of the Employment Agreement; under any provision of the Employment Agreement that survives the termination of that agreement; under any applicable workers’ compensation statute; under any option, restricted share or other agreement concerning any equity interest in the Company; as a shareholder of the Company or any other right that is not waivable under applicable law.

I acknowledge that, among other rights, I am waiving and releasing any rights I may have under ADEA, that this Release and Waiver is knowing and voluntary, and that the consideration given for this Release and Waiver is in addition to anything of value to which I was already entitled as an executive of the Company. If I am 40 years of age or older upon execution of this Release and Waiver, I further acknowledge that I have been advised, as required by the Older Workers Benefit Protection Act, that: (a) the release
and waiver granted herein does not relate to claims under the ADEA which may arise after this Release and Waiver is executed; (b) I should consult with an attorney prior to executing this Release and Waiver; and (c) I have twenty-one (21) days from the date of termination of my employment with the Company in which to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier); (d) I have seven (7) days following the execution of this Release and Waiver to revoke my consent to this Release and Waiver; and (e) this Release and Waiver shall not be effective until the seven (7) day revocation period has expired unexercised. If I am less than 40 years of age upon execution of this Release and Waiver, I acknowledge that I have the right to consult with an attorney prior to executing this Release and Waiver (although I may choose voluntarily not to do so); and (e) I have five (5) days from the date of termination of my employment with the Company in which to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier).

I acknowledge my continuing obligations under my Confidential Information and Inventions Agreement dated ________, ______. Pursuant to the Confidential Information and Inventions Agreement I understand that among other things, I must not use or disclose any confidential or proprietary information of the Company and I must immediately return all Company property and documents (including all embodiments of proprietary information) and all copies thereof in my possession or control. I understand and agree that my right to the payments and other benefits I am receiving in exchange for my agreement to the terms of this Release and Waiver is contingent upon my continued compliance with my Confidential Information and Inventions Agreement.

This Release and Waiver, including my Confidential Information and Inventions Agreement dated ________, ______, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company that is not expressly stated herein. This Release and Waiver may only be modified by a writing signed by both me and a duly authorized officer of the Company.

Date:

By: Barry Moze
This Executive Employment Agreement (hereinafter referred to as the “Agreement”), is entered into by and between Horizon Pharma, Inc., a Delaware corporation, and its wholly owned subsidiary, Horizon Pharma USA, Inc., a Delaware corporation, each having a principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, IL 60015, (hereinafter referred to together as the “Company”) and John Kody (hereinafter referred to as the “Executive”). The terms of this Agreement shall remain confidential until the Executive’s first day of employment with the Company (the “Date of Hire”), which will be on November 24, 2014 and which is also the effective date of this Agreement (the “Effective Date”).

RECITALS

WHEREAS, Company desires assurance of the association and services of the Executive in order to retain the Executive’s experience, skills, abilities, background and knowledge, and is willing to engage the Executive’s services on the terms and conditions set forth in this Agreement; and

WHEREAS, Executive desires to be in the employ of the Company, and is willing to accept such employment on the terms and conditions set forth in this Agreement.

AGREEMENT

1. Employment

1.1 Term. The Company hereby agrees to employ the Executive, and the Executive hereby accepts employment by the Company, upon the terms and conditions set forth in this Agreement. Executive’s employment shall be governed under the terms set forth in this Agreement beginning on the Effective Date and shall continue until it is terminated pursuant to Section 4 herein (hereinafter referred to as the “Term”).

1.2 Title. The Executive shall have the title of Executive Vice President, Chief Commercial Officer of the Company (such position held by Executive during such period is hereinafter referred to as “CCO”) and Executive shall serve in such other capacity or capacities commensurate with his position as CCO as the President and CEO of the Company may from time to time prescribe.

1.3 Duties. The Executive shall do and perform all services, acts or things necessary or advisable to manage and conduct the business of the Company and shall have the authority and responsibilities which are generally associated with the position of CCO including being responsible for the Company’s commercial strategy and operations. The Executive shall report to the President and CEO.
1.4 Policies and Practices. The employment relationship between the Parties shall be governed by this Agreement and the policies and practices established by the Company and the Board of Directors (hereinafter referred to as the “Board”). In the event that the terms of this Agreement differ from or are in conflict with the Company’s policies or practices or the Company’s Employee Handbook, this Agreement shall control.

1.5 Location. The Executive shall perform the services the Executive is required to perform pursuant to this Agreement in the headquarters office for the Company in the Deerfield, Illinois area. The Company may from time to time require the Executive to travel temporarily to other locations outside of the Deerfield, Illinois area in connection with the Company’s business.

2. Loyalty of Executive.

2.1 Loyalty. During the Executive’s employment by the Company, the Executive shall devote the Executive’s business energies, interest, abilities and productive time to the proper and efficient performance of Executive’s duties under this Agreement. Subject to the prior written consent of the President and CEO, the Executive is permitted to serve on the board of directors of one other company, so long as the other company does not compete with the Company.

2.2 Exclusive Employment. Except with the prior written consent of the Board, Executive shall not, during the term of this Agreement, undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor. Executive may engage in any civic and not-for-profit activities so long as such activities do not materially interfere with the performance of his duties hereunder or present a conflict of interest with the Company.

2.3 Agreement not to Participate in Company’s Competitors. During the Term of this Agreement, the Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known by Executive to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise or in any company, person or entity that is, directly or indirectly, in competition with the business of the Company or any of its affiliates. Notwithstanding the foregoing, Executive may invest and/or maintain investments in any public or private entity up to an amount of 2% of an entity’s fully diluted shares and on a passive basis.
3. **Compensation to Executive.**

3.1 **Base Salary.** The Company shall pay the Executive a base salary at the initial annualized rate of four hundred twenty seven thousand dollars ($427,000.00) per year, subject to standard deductions and withholdings, or such higher rate as may be determined from time to time by the Board or the compensation committee thereof (hereinafter referred to as the “*Base Salary*”). Such Base Salary shall be paid in accordance with the Company’s standard payroll practice. Payments of salary installments shall be made no less frequently than once per month. Executive’s Base Salary will be reviewed annually each December and Executive shall be eligible to receive a salary increase (but not decrease) annually in an amount to be determined by the Board or the compensation committee thereof in its sole and exclusive discretion. Once increased, the new salary shall become the Base Salary for purposes of this Agreement and shall not be reduced without the Executive’s written consent. Any material reduction in the Base Salary of the Executive, without his written consent, may be deemed Good Reason as set forth in and subject to Section 4.5.2 of this Agreement.

3.2 **Discretionary Bonus.** Provided the Executive meets the conditions stated in this Section 3.2, the Executive shall be eligible for an annual discretionary bonus (hereinafter referred to as the “*Bonus*”) with a target amount of fifty percent (50%) of the Executive’s Base Salary, subject to standard deductions and withholdings, based on the Board’s determination, in good faith, and based upon the Executive’s individual achievement and company performance objectives as set by the Board or the compensation committee thereof, of whether the Executive has met such performance milestones as are established for the Executive by the Board or the compensation committee thereof, in good faith, in consultation with the Executive (hereinafter referred to as the “*Performance Milestones*”). The Performance Milestones will be based on certain factors including, but not limited to, the Executive’s performance and the Company’s financial performance. The Executive’s Bonus target will be reviewed annually and may be adjusted by the Board or the compensation committee thereof in its discretion, provided however, that the Bonus target may only be materially reduced upon Executive’s written consent. The Executive must be employed on the date the Bonus is awarded to be eligible for the Bonus, subject to the termination provisions thereof. The Bonus shall be paid during the calendar year following the performance calendar year.
3.3 Equity Awards. At the next scheduled Compensation Committee meeting that follows the Date of Hire the Executive will be granted the following equity awards pursuant to and subject to the terms of the Company’s 2011 Equity Incentive Plan and its form of stock option and restricted stock unit award agreements, in the forms provided to Executive concurrently with this Agreement (collectively the “Equity Plan Documents”) and compliance with applicable securities laws:

3.3.1 New Hire Option. A stock option to purchase up to 128,000 shares of the Company’s common stock (the “Option”). The Option will have an exercise price equal to the fair market value of the Company’s common stock on the applicable date of grant. Subject to Executive’s continued provision of services to the Company through the applicable vesting dates, the Option shall vest as follows: 25% of the total number of shares subject to the Option shall vest on the first anniversary of the Date of Hire and 1/36 of the remaining number of shares subject to the Option shall vest on each monthly anniversary thereafter so that the Option would fully vest on the four (4) year anniversary of the Date of Hire subject to Executive’s continued services with the Company through such date.

3.3.2 New Hire Restricted Stock Unit Award. A restricted stock unit award in respect of 75,900 shares of the Company’s common stock (the “RSU Award”). Subject to Executive’s continued provision of services to the Company through the applicable vesting dates, the RSU Award shall vest as follows: 25% of the total number of units subject to the RSU Award shall vest on each anniversary of the Date of Hire so that the RSU Award would fully vest on the four (4) year anniversary of the Date of Hire subject to Executive’s continued services with the Company through such date.

3.4 Sign-on Bonus. Within thirty (30) days of the Executive’s Date of Hire, Executive will be paid a one-time bonus of one hundred fifty thousand dollars ($150,000.00) (the “Sign-on Bonus”), subject to standard deductions and withholdings. The Sign-on bonus is intended to compensate the Executive for the annual bonus forfeited upon termination with his former company. If, prior to the first anniversary of the Date of Hire, Executive resigns for any reason other than for Good Reason, or the Company terminates his employment for Cause, Employee must repay to the Company, on or within thirty (30) days after the employment termination date, an amount equal to the Sign-on Bonus.

3.5 Legal Review. Upon the Executive’s submission of appropriate itemized proof and verification of reasonable and customary legal fees incurred by the Executive in obtaining legal advice associated with the review, preparation, approval, and execution of this Agreement, the Company shall pay for up to $10,000.00 of such legal fees subject to receipt of appropriate proof and verification of such legal fees no later than sixty (60) days of receipt of an invoice for legal services from the Executive and/or his attorneys. To be eligible for reimbursement, the invoice must be submitted no later than ninety (90) days after the legal fees are incurred.

3.6 Changes to Compensation. The Executive’s compensation may be changed from time to time by mutual agreement of the Executive and the Company. In the event that the Executive’s base salary is materially decreased without his written consent, said decrease will be Good Reason for the Executive to terminate the Agreement as set forth in and subject to Section 4.5.2 of this Agreement.
3.7 Taxes. All amounts paid under this Agreement to the Executive by the Company will be paid less applicable tax withholdings and any other withholdings required by law or authorized by the Executive.

3.8 Benefits. The Executive shall, in accordance with Company policy and the terms of the applicable plan documents, be eligible to participate in benefits under any executive benefit plan or arrangement which may be in effect from time to time and made available to the Company’s executives or key management employees, provided, however, that the Executive shall be entitled to at least four (4) weeks of paid vacation annually.

3.9 Vidara Transaction Section 4985 Gross-Up. To the extent that the Company agrees to reimburse any of the executive officers of the Company for any excise tax imposed upon them pursuant to Section 4985 of the Code in connection with the Company’s proposed strategic transaction with Vidara Therapeutics International Ltd., including any reimbursement for income taxes imposed upon such excise tax reimbursement, the Executive shall be entitled to be reimbursed on the same basis as the other executive officers.

4. Termination

4.1 Termination by the Company. The Executive’s employment with the Company may be terminated only under the following conditions:

4.1.1 Termination for Death or Disability. The Executive’s employment with the Company shall terminate effective upon the date of the Executive’s death or “Complete Disability” (as defined in Section 4.5.1), provided, however, that this Section 4.1.1 shall in no way limit the Company’s obligations to provide such reasonable accommodations to the Executive and/or his heirs as may be required by law.

4.1.2 Termination by the Company For Cause. The Company may terminate the Executive’s employment under this Agreement for “Cause” (as defined in Section 4.5.3) by delivery of written notice to the Executive specifying the Cause or Causes relied upon for such termination, provided that such notice is delivered within two (2) months following the occurrence or discovery of any event or events constituting “Cause”. Any notice of termination given pursuant to this Section 4.1.2 shall effect termination as of the date of the notice or such date as specified in the notice. The Executive shall have the right to appear before the CEO before any termination for Cause becomes effective and binding upon the Executive.

4.1.3 Termination by the Company Without Cause. The Company may terminate the Executive’s employment under this Agreement at any time and for any reason or no reason subject to the requirements set out in Section 4.4 of this Agreement. Such termination shall be effective on the date the Executive is so informed or as otherwise specified by the Company, pursuant to notice requirements set forth in Section 6 of this Agreement.
4.2 Termination By The Executive. The Executive may terminate his employment with the Company at any time and for any reason or no reason, including, but not limited, to the following conditions:

4.2.1 Good Reason. The Executive may terminate his employment under this Agreement for “Good Reason” (as defined below in Section 4.5.2) by delivery of written notice to the Company specifying the Good Reason relied upon by the Executive for such termination in accordance with the requirements of such section.

4.2.2 Without Good Reason. The Executive may terminate the Executive’s employment hereunder for other than Good Reason upon thirty (30) days written notice to the Company.

4.3 Termination by Mutual Agreement of the Parties. The Executive’s employment pursuant to this Agreement may be terminated at any time upon a mutual agreement in writing of the Parties. Any such termination of employment shall have the consequences specified in such mutual agreement.

4.4 Compensation to Executive Upon Termination. In connection with any termination of the Executive’s employment for any reason, the Executive or the Executive’s estate, as applicable, shall be entitled to any amounts payable to the Executive or the Executive’s beneficiaries subject to and accordance with the terms of the Company’s employee welfare benefit plans or policies (excluding any severance pay).

4.4.1 Death or Complete Disability. If the Executive’s employment shall be terminated by death or Complete Disability as provided in Section 4.1.1, the Company shall pay to Executive, and/or Executive’s heirs, all earned but unpaid Base Salary, any earned but unpaid discretionary bonuses for any prior period at such time as bonuses would have been paid if the Executive remained employed, all accrued but unpaid business expenses, and all accrued but unused vacation time earned through the date of termination at the rate in effect at the time of termination (hereinafter referred to as the “Accrued Amounts”), less standard deductions and withholdings. The Executive shall also be eligible to receive a pro-rated bonus for the year of termination, as determined by the Board or the Compensation Committee of the Board based on actual performance and the period of the year he was employed (hereinafter referred to as the “Pro-rata Bonus”), less standard deductions and withholdings, to be paid as a lump sum within thirty (30) days after the date of termination.

4.4.2 With Cause or Without Good Reason. If the Executive’s employment shall be terminated by the Company for Cause, or if the Executive terminates employment hereunder without Good Reason, the Company shall pay the Executive’s Base Salary, accrued but unpaid business expenses and accrued and unused vacation benefits earned through the date of termination at the rate in effect at the time of termination, less standard deductions and withholdings.
4.4.3 Without Cause or For Good Reason.

(i) Not in Connection With a Change in Control. If the Company terminates the Executive’s employment without Cause or the Executive terminates his employment for Good Reason, and Section 4.4.3(ii) below does not apply, the Company shall pay the Accrued Amounts subject to standard deductions and withholdings, to be paid as a lump sum no later than thirty (30) days after the date of termination. In addition, subject to the limitations stated in this Agreement and upon the Executive’s furnishing to the Company an executed waiver and release of claims (the form of which is attached hereto as Exhibit A) (the “Release”) within the applicable time period set forth therein, but in no event later than forty-five days following termination of employment and permitting such Release to become effective in accordance with its terms (the “Release Effective Date”), and subject to Executive entering into no later than the Release Effective Date a non-competition agreement to be effective during the Severance Period (as defined below), substantially similar to Section 2.3, and continuing to abide by its terms during the Severance Period, the Executive shall be entitled to:

(a) the equivalent of the Executive’s Base Salary in effect at the time of termination will continue to be paid for a period of twelve (12) months following the date of termination (hereinafter referred to as the “Severance Period”), less standard deductions and withholdings, to be paid during the Severance Period according to the Company’s regular payroll practices, subject to any delay in payment required by Section 4.6 in connection with the Release Effective Date; and

(b) in the event the Executive timely elects continued coverage under COBRA, the Company will continue to pay the same portion of Executive’s COBRA health insurance premium as the percentage of health insurance premiums that it paid during the Executive’s employment, including any amounts that Company paid for benefits to the qualifying family members of the Executive, following the date of termination up until the earlier of either (i) the last day of the Severance Period or, (ii) the date on which the Executive begins full-time employment with another company or business entity which offers comparable health insurance coverage to the Executive (such period, the “COBRA Payment Period”). Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Executive a taxable cash amount, which payment shall be made regardless of whether the Executive or his qualifying family members elect COBRA continuation coverage (the “Health Care Benefit Payment”). The Health Care Benefit Payment shall be paid in monthly or bi-weekly installments on the same schedule that the COBRA premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company otherwise would have paid for COBRA insurance premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the COBRA Payment Period.
(ii) In Connection With a Change in Control. If the Company (or its successor) terminates the Executive’s employment without Cause or the Executive terminates his employment for Good Reason within the period commencing ninety (90) days immediately prior to a Change in Control of the Company and ending eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the Executive shall receive the Accrued Amounts subject to standard deductions and withholdings, to be paid as a lump sum no later than thirty (30) days after the date of termination. In addition, subject to the limitations stated in this Agreement and upon the Executive’s furnishing to the Company (or its successor) an executed Release within the applicable time period set forth therein, but in no event later than forty-five days following termination of employment and permitting such Release to become effective in accordance with its terms, and subject to Executive entering into no later than the Release Effective Date a non-competition agreement to be effective during the Severance Period, substantially similar to Section 2.3, and continuing to abide by its terms during the Severance Period, then in lieu of (and not additional to) the benefits provided pursuant to Section 4.4.3(i) above, the Executive shall be entitled to:

(a) the equivalent of the Executive’s Base Salary in effect at the time of termination will continue to be paid during the Severance Period, less standard deductions and withholdings, to be paid during the Severance Period according to the Company’s regular payroll practices, subject to any delay in payment required by Section 4.6 in connection with the Release Effective Date;

(b) Executive’s target Bonus in effect at the time of termination, or if none, the last target Bonus in effect for Executive, less standard deductions and withholdings, to be paid in a lump sum within ten (10) days following the later of (i) the Release Effective Date, or (ii) the effective date of the Change in Control; and

(c) in the event the Executive timely elects continued coverage under COBRA, the Company will continue to pay the same portion of Executive’s COBRA health insurance premium as the percentage of health insurance premiums that it paid during the Executive’s employment, including any amounts that Company paid for benefits to the qualifying family members of the Executive, following the date of termination until the expiration of the COBRA Payment Period. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Executive the Health Care Benefit Payment, which payment shall be made regardless of whether the Executive or his qualifying family members elect COBRA continuation coverage. The Health Care Benefit Payment shall be paid in monthly or bi-weekly installments on the same schedule that the COBRA premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company otherwise would have paid for COBRA insurance premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the COBRA Payment Period.
(iii) No Duplication of Benefits. For the avoidance of doubt, in no event will Executive be entitled to benefits under Section 4.4.3(i) and Section 4.4.3(ii). If Executive commences to receive benefits under Section 4.4.3(i) due to a qualifying termination prior to a Change in Control and thereafter becomes entitled to benefits under Section 4.4.3(ii), any benefits previously provided to Executive under Section 4.4.3(i) shall offset the benefits to be provided to Executive under Section 4.4.3(ii) and shall be deemed to have been provided to Executive pursuant to Section 4.4.3(ii).

4.4.4 Equity Award Acceleration.

(i) In Connection With a Change in Control. In the event that the Executive’s employment is terminated without Cause or for Good Reason within the ninety (90) days immediately preceding or during the eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the vesting of the Option, the RSU Award and any other Company equity awards granted to Executive shall be fully accelerated such that on the effective date of such termination (or, if later, the date of the Change in Control) one hundred percent (100%) of the equity award shares granted to Executive prior to such termination shall be fully vested and immediately exercisable, if applicable, by the Executive.

(ii) Release and Waiver. Any equity vesting acceleration pursuant to this Section 4.4.4 shall be conditioned upon and subject to the Executive’s delivery to the Company of a fully effective Release in accordance with the terms specified by Section 4.4.3 hereof and such vesting acceleration benefit shall be in addition to the benefits provided by Section 4.4.3 hereof.

4.5 Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

4.5.1 Complete Disability. “Complete Disability” shall mean the inability of the Executive to perform the Executive’s duties under this Agreement, whether with or without reasonable accommodation, because the Executive has become permanently disabled within the meaning of any policy of disability income insurance covering employees of the Company then in force. In the event the Company has no policy of disability income insurance covering employees of the Company in force when the Executive becomes disabled, the term “Complete Disability” shall mean the inability of the Executive to perform the Executive’s duties under this Agreement, whether with or without reasonable accommodation, by reason of any incapacity, physical or mental, which the Board, based upon medical advice or an opinion provided by a licensed physician, determines to have incapacitated the Executive from satisfactorily performing all of the Executive’s usual services for the Company, with or without reasonable accommodation, for a period of at least one hundred eighty (180) days during any twelve (12) month period that need not be consecutive.
4.5.2 Good Reason. “Good Reason” for the Executive to terminate the Executive’s employment hereunder shall mean the occurrence of any of the following events without the Executive’s consent:

(i) a material reduction in the Executive’s duties, authority, or responsibilities relative to the duties, authority, or responsibilities in effect immediately prior to such reduction, including by way of example, having the same title, duties, authority and responsibilities at a subsidiary level following a Change in Control;

(ii) the relocation of the Executive’s primary work location to a point more than fifty (50) miles from the Executive’s current work location set forth in Section 1.5 that requires a material increase in Executive’s one-way driving distance;

(iii) a material reduction by the Company of the Executive’s base salary or annual target Bonus opportunity, without the written consent of the Executive, as initially set forth herein or as the same may be increased from time to time pursuant to this Agreement; and

(iv) a material breach by the Company of Section 1.2 of this Agreement.

Provided, however that, such termination by the Executive shall only be deemed for Good Reason pursuant to the foregoing definition if (i) the Company is given written notice from the Executive within sixty (60) days following the first occurrence of the condition that he considers to constitute Good Reason describing the condition and the Company fails to satisfactorily remedy such condition within thirty (30) days following such written notice, and (ii) the Executive terminates employment within thirty (30) days following the end of the period within which the Company was entitled to remedy the condition constituting Good Reason but failed to do so.

4.5.3 Cause. “Cause” for the Company to terminate Executive’s employment hereunder shall mean the occurrence of any of the following events, as determined reasonably and in good faith by the Board or a committee designated by the Board:

(i) the Executive’s gross negligence or willful failure to substantially perform his duties and responsibilities to the Company or willful and deliberate violation of a Company policy;

(ii) the Executive’s conviction of a felony or the Executive’s commission of any act of fraud, embezzlement or dishonesty against the Company or involving moral turpitude that is likely to inflict or has inflicted material injury on the business of the Company, to be determined by the sole discretion of the Company;

(iii) the Executive’s unauthorized use or disclosure of any proprietary information or trade secrets of the Company or any other party that the Executive owes an obligation of nondisclosure as a result of the Executive’s relationship with the Company; and
(iv) the Executive’s willful and deliberate breach of the obligations under this Agreement that causes material injury to the business of the Company.

4.5.4 Change in Control. For purposes of this Agreement, “Change in Control” means: (i) a sale of all or substantially all of the assets of the Company; (ii) a merger or consolidation in which the Company is not the surviving entity and in which the holders of the Company’s outstanding voting stock immediately prior to such transaction own, immediately after such transaction, securities representing less than fifty percent (50%) of the voting power of the entity surviving such transaction or, where the surviving entity is a wholly-owned subsidiary of another entity, the surviving entity’s parent; (iii) a reverse merger in which the Company is the surviving entity but the shares of Common Stock outstanding immediately preceding the merger are converted by virtue of the merger into other property, whether in the form of securities of the surviving entity’s parent, cash or otherwise, and in which the holders of the Company’s outstanding voting stock immediately prior to such transaction own, immediately after such transaction, securities representing less than fifty percent (50%) of the voting power of the Company or, where the Company is a wholly-owned subsidiary of another entity, the Company’s parent; or (iv) an acquisition by any person, entity or group (excluding any employee benefit plan, or related trust, sponsored or maintained by the Company or subsidiary of the Company or other entity controlled by the Company) of the beneficial ownership of securities of the Company representing at least seventy-five percent (75%) of the combined voting power entitled to vote in the election of Directors; provided, however, that nothing in this paragraph shall apply to a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company.

4.6 Application of Internal Revenue Code Section 409A. Notwithstanding anything to the contrary set forth herein, any payments and benefits provided under this Agreement (the “Severance Benefits”) that constitute “deferred compensation” within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the “Code”) and the regulations and other guidance thereunder and any state law of similar effect (collectively “Section 409A”) shall not commence in connection with Executive’s termination of employment unless and until Executive has also incurred a “separation from service” (as such term is defined in Treasury Regulation Section 1.409A-1(h) (“Separation From Service”), unless the Company reasonably determines that such amounts may be provided to Executive without causing Executive to incur the additional 20% tax under Section 409A.

It is intended that each installment of the Severance Benefits payments provided for in this Agreement is a separate “payment” for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that payments of the Severance Benefits set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulation Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if the Company
(or, if applicable, the successor entity thereto) determines that the Severance Benefits constitute “deferred compensation” under Section 409A and Executive is, on the termination of service, a “specified employee” of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Severance Benefit payments shall be delayed until the earlier to occur of (i) the date that is six months and one day after Executive’s Separation From Service, or (ii) the date of Executive’s death (such applicable date, the “Specified Employee Initial Payment Date”), the Company (or the successor entity thereto, as applicable) shall (A) pay to Executive a lump sum amount equal to the sum of the Severance Benefit payments that Executive would otherwise have received through the Specified Employee Initial Payment Date if the commencement of the payment of the Severance Benefits had not been so delayed pursuant to this Section and (B) commence paying the balance of the Severance Benefits in accordance with the applicable payment schedules set forth in this Agreement.

Notwithstanding anything to the contrary set forth herein, Executive shall receive the Severance Benefits described above, if and only if Executive duly executes and returns to the Company within the applicable time period set forth therein, but in no event more than forty-five days following Separation From Service, the Company’s standard form of release of claims in favor of the Company (attached to this Agreement as Exhibit A) (the “Release”) and permits the release of claims contained therein to become effective in accordance with its terms (such latest permitted date, the “Release Deadline”). If the severance benefits are not covered by one or more exemptions from the application of Section 409A and the Release could become effective in the calendar year following the calendar year in which Executive separates from service, the Release will not be deemed effective any earlier than the Release Deadline. Notwithstanding any other payment schedule set forth in this Agreement, none of the Severance Benefits will be paid or otherwise delivered prior to the effective date (or deemed effective date) of the Release. Except to the extent that payments may be delayed until the Specified Employee Initial Payment Date pursuant to the preceding paragraph, on the first regular payroll pay day following the effective date of the Release, the Company will pay Executive the Severance Benefits Executive would otherwise have received under the Agreement on or prior to such date but for the delay in payment related to the effectiveness of the Release, with the balance of the Severance Benefits being paid as originally scheduled.

The severance benefits are intended to qualify for an exemption from application of Section 409A or comply with its requirements to the extent necessary to avoid adverse personal tax consequences under Section 409A, and any ambiguities herein shall be interpreted accordingly.

4.7 Application of Internal Revenue Code Section 280G. If any payment or benefit Executive would receive pursuant to a Change in Control from the Company or otherwise (“Payment”) would (i) constitute a “parachute payment” within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999
of the Code (the “Excise Tax”), then such Payment shall be equal to the Reduced Amount. The “Reduced Amount” shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive’s receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting “parachute payments” is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, Executive agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, Executive will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

Unless Executive and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

The Company shall use commercially reasonable efforts to cause the accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Executive and the Company within fifteen (15) calendar days after the date on which Executive’s right to a Payment is triggered (if requested at that time by Executive or the Company) or such other time as requested by Executive or the Company.

4.8 Indemnification Agreement. Concurrently with the execution of this Agreement, the Company and the Executive shall enter into an indemnification agreement, a copy of which is attached hereto as Exhibit B.

4.9 Confidential Information and Invention Assignment Agreement. Concurrently with the execution of this Agreement, the Executive shall execute the Company’s Confidential Information and Invention Assignment Agreement, a copy of which is attached as Exhibit C.
4.10 No Mitigation or Offset. The Executive shall not be required to seek or accept other employment, or otherwise to mitigate damages, as a condition to receipt of the Severance Benefits, and the Severance Benefits shall not be offset by any amounts received by the Executive from any other source, except to the extent that the Executive’s right the benefits described in Sections 4.4.3(i)(b) or 4.4.3(ii)(c), as applicable, are terminated by reason of the Executive obtaining full-time employment with another company or business entity which offers comparable health insurance coverage.

5. Assignment and Binding Effect.

This Agreement shall be binding upon the Executive and the Company and inure to the benefit of the Executive and the Executive’s heirs, executors, personal representatives, assigns, administrators and legal representatives. Because of the unique and personal nature of the Executive’s duties under this Agreement, neither this Agreement nor obligations under this Agreement shall be assignable by the Executive. This Agreement shall be binding upon and inure to the benefit of the Company and its successors, assigns and legal representatives, provided that the Agreement may only be assigned to an acquirer of all or substantially all of the Company’s assets. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, “successor” means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company.


For the purposes of this Agreement, notices, demands, and all other forms of communication provided for in this Agreement shall be in writing and shall be deemed to have been duly given when delivered or (unless otherwise specified) mailed by registered mail, return receipt requested, postage prepaid, or by confirmed facsimile, addressed as set forth below, or to such other address as any party may have furnished to the other in writing in accordance herewith, except that notices of address shall be effective only upon receipt, as follows:

If to the Company:
Horizon Pharma, Inc.
520 Lake Cook Road, Suite 520
Deerfield, IL 60015
Attention: Timothy P. Walbert, Chairman, President & CEO
Fax: 847-572-1372

If to the Executive:
John Kody
330 Brampton Court
Lake Forest, IL 60045
Any such written notice shall be deemed given on the earlier of the date on which such notice is personally delivered or five (5) days after its deposit in the United States mail as specified above. Either Party may change its address for notices by giving written notice to the other Party in the manner specified in this section.

7. **Choice of Law.**
   
   This Agreement shall be governed by the laws of the State of Illinois, without regard to any conflicts of law principals thereof that would call for the application of the laws of any other jurisdiction. The Parties consent to the exclusive jurisdiction and venue of the federal court in the Northern District of Illinois, and state courts located in the state of Illinois, county of Cook. Nothing in this Section 7 limits the rights of the Parties to seek appeal of a decision of an Illinois court outside of Illinois that has proper jurisdiction over the decision of a court sitting in Illinois.

8. **Integration.**
   
   This Agreement, including Exhibit A, Exhibit B, Exhibit C and the Equity Plan Documents, contains the complete, final and exclusive agreement of the Parties relating to the terms and conditions of the Executive’s employment and the termination of Executive’s employment, and supersedes all prior and contemporaneous oral and written employment agreements or arrangements between the Parties.

9. **Amendment.**
   
   This Agreement cannot be amended or modified except by a written agreement signed by the Executive and the Company.

10. **Waiver.**
    
    No term, covenant or condition of this Agreement or any breach thereof shall be deemed waived, except with the written consent of the Party against whom the waiver is claimed, and any waiver or any such term, covenant, condition or breach shall not be deemed to be a waiver of any preceding or succeeding breach of the same or any other term, covenant, condition or breach.

11. **Severability.**
    
    The finding by a court of competent jurisdiction of the unenforceability, invalidity or illegality of any provision of this Agreement shall not render any other provision of this Agreement unenforceable, invalid or illegal. Such court shall have the authority to modify or replace the invalid or unenforceable term or provision with a valid and enforceable term or provision, which most accurately represents the Parties' intention with respect to the invalid, unenforceable, or illegal term or provision.
12. **Interpretation; Construction.**

The headings set forth in this Agreement are for convenience of reference only and shall not be used in interpreting this Agreement. This Agreement has been drafted and negotiated by legal counsel representing the Company and the Executive. The Parties acknowledge that each Party and its counsel has reviewed and revised, or had an opportunity to review and revise, this Agreement, and any rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Agreement.

13. **Execution by Facsimile Signatures and in Counterparts.**

The parties agree that facsimile signatures shall have the same force and effect as original signatures. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

14. **Survival.**

The provisions of this Agreement, and of all other agreements referenced herein, shall survive the termination of this Agreement, and of the Executive’s employment by the Company for any reason, to the extent necessary to enable the parties to enforce their respective rights hereunder.
IN WITNESS WHEREFORE, the parties have signed this Agreement on the date first written above.

COMPANY:

HORIZON PHARMA, INC.
HORIZON PHARMA USA, INC.

By:

Title: Chairman, President & CEO

Print Name: Timothy P. Walbert

/s/ Timothy P. Walbert

Signature:

As authorized agent of the Company

October 30, 2014

Date

EXECUTIVE:

John Kody

/s/ John Kody

John Kody, individually

October 30, 2014

Date
In consideration of the payments and other benefits set forth in Section 4.4 of the Executive Employment Agreement dated 2014, (the “Employment Agreement”), to which this form is attached, I, John Kody, hereby furnish Horizon Pharma, Inc. and Horizon Pharma USA, Inc. (together the “Company”), with the following release and waiver (“Release and Waiver”).

In exchange for the consideration provided to me by the Employment Agreement that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, Affiliates, and assigns from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring relating to my employment or the termination thereof prior to my signing this Release and Waiver. This general release includes, but is not limited to: (1) all claims arising out of or in any way related to my employment with the Company or the termination of that employment; (2) all claims related to my compensation or benefits from the Company, including, but not limited to, salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership interests in the Company; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (4) all tort claims, including, but not limited to, claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims, including, but not limited to, claims for discrimination, harassment, retaliation, attorneys’ fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) (“ADEA”), the Illinois Human Rights Act, the Illinois Equal Pay Act, the Illinois Religious Freedom Restoration Act, and the Illinois Genetic Information Privacy Act. Notwithstanding the foregoing, this Release and Waiver, shall not release or waive my rights: to indemnification under the articles and bylaws of the Company or applicable law; to payments under Sections _______ of the Employment Agreement; under any provision of the Employment Agreement that survives the termination of that agreement; under any applicable workers’ compensation statute; under any option, restricted share or other agreement concerning any equity interest in the Company; as a shareholder of the Company or any other right that is not waivable under applicable law.

I acknowledge that, among other rights, I am waiving and releasing any rights I may have under ADEA, that this Release and Waiver is knowing and voluntary, and that the consideration given for this Release and Waiver is in addition to anything of value to which I was already entitled as an executive of the Company. If I am 40 years of age or older upon execution of this Release and Waiver, I further acknowledge that I have been advised, as required by the Older Workers Benefit Protection Act, that: (a) the release
and waiver granted herein does not relate to claims under the ADEA which may arise after this Release and Waiver is executed; (b) I should consult with an attorney prior to executing this Release and Waiver; and (c) I have twenty-one (21) days from the date of termination of my employment with the Company in which to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier); (d) I have seven (7) days following the execution of this Release and Waiver to revoke my consent to this Release and Waiver; and (e) this Release and Waiver shall not be effective until the seven (7) day revocation period has expired unexercised. If I am less than 40 years of age upon execution of this Release and Waiver, I acknowledge that I have the right to consult with an attorney prior to executing this Release and Waiver (although I may choose voluntarily not to do so); and (e) I have five (5) days from the date of termination of my employment with the Company in which to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier).

I acknowledge my continuing obligations under my Confidential Information and Inventions Agreement dated ________, 2014. Pursuant to the Confidential Information and Inventions Agreement I understand that among other things, I must not use or disclose any confidential or proprietary information of the Company and I must immediately return all Company property and documents (including all embodiments of proprietary information) and all copies thereof in my possession or control. I understand and agree that my right to the payments and other benefits I am receiving in exchange for my agreement to the terms of this Release and Waiver is contingent upon my continued compliance with my Confidential Information and Inventions Agreement.

This Release and Waiver, including my Confidential Information and Inventions Agreement dated ________, 2014, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company that is not expressly stated herein. This Release and Waiver may only be modified by a writing signed by both me and a duly authorized officer of the Company.

Date:
By: John Kody
1. Purpose. The Horizon Pharma Public Limited Company Cash Long Term Incentive Program (the “Program”) is for purposes of providing cash incentive compensation to individuals who make a significant contribution to the performance of Horizon Pharma Public Limited Company (the “Company”) and its Affiliates and who are selected for participation in the Program (the “Designated Participants”). The Program objectives are to: (a) provide additional motivation to the Designated Participants to focus on our long-term corporate performance, (b) provide an additional retention incentive for Designated Participants, and (c) further align the interests of the Designated Participants with those of our shareholders. Defined terms not explicitly defined in this Program document including its attached APPENDIX A but defined in the Equity Incentive Plan will have the same definitions as in the Equity Incentive Plan.

2. How Awards Are Earned Under the Program.

(a) General Program Description. The Program provides the opportunity for the Designated Participants to earn a cash bonus based on the Company’s level of attainment of performance goals as specified below in Section 2(d) (the “Performance Goals”) during the period of time that begins on November 5, 2014 and ends on November 4, 2017 (the “Performance Period”). If the Performance Goals are not achieved during the Performance Period, the Designated Participants will not earn any cash bonus under the Program. To the maximum extent possible, payments made under the Program are intended to qualify as “Performance Cash Awards” under the Equity Incentive Plan.

(b) Maximum Award; Actual Award. The maximum cash bonus that a Designated Participant is eligible to earn under the Program will in no event exceed his or her maximum award amount specified on the attached APPENDIX B under the “TSR Level 60%” column next to the name of such Designated Participant (the “Maximum Award”). The Actual Award earned by and payable to each Participant under the Program will be determined by the Committee in accordance with the terms of this Program.

(c) Designated Participants. The Program’s Designated Participants were approved by the Committee on November 5, 2014 and are as specified on APPENDIX B. Except as provided in this Program, no Employee has any right (i) to be a Designated Participant in the Program, (ii) to continue as a Designated Participant, or (iii) to be granted a potential Maximum Award or to earn an Actual Award under the Program.

(d) Performance Goals and Performance Period. Actual Award amounts will be calculated based upon the Committee’s determination of the Company’s level of attainment of the Performance Goals during the Performance Period pursuant to the following criteria:

(i) The Actual Award amount will be calculated based on the TSR from November 5, 2014 to May 6, 2015 (the “Measurement Period”). VWAP will be used to calculate the TSR. In order for any Actual Award to be earned under the Program, the TSR during the Measurement Period must be greater than or equal to 15% (the “Measurement Period Threshold Goal”) or a Change in Control must occur prior to expiration of the Measurement Period. The VWAP on November 5, 2014 was $12.08, so the minimum VWAP that is required on May 6, 2015 for the Measurement Period Threshold Goal to be attained is $12.95 (assuming no dividends or distributions are made or declared in respect of the Company’s ordinary shares during the Measurement Period). If the VWAP on May 6, 2015 is less than $12.95, no Actual Awards will be paid under the Program and the Program will immediately terminate following completion of the Measurement Period without payment to any Designated Participant (unless a Change in Control occurs prior to expiration of the Measurement Period).
(ii) If the Measurement Period Threshold Goal is attained, the determined Actual Award amount for each Designated Participant will correspond to the applicable corresponding award level set forth on the schedule on the attached APPENDIX B for such Designated Participant based upon the percentage of TSR attained during the Measurement Period as determined pursuant to the table below (assuming no dividends or distributions are made or declared in respect of the Company’s ordinary shares during the Measurement Period):

<table>
<thead>
<tr>
<th>TSR from 11/5/14 to 5/6/15</th>
<th>VWAP on 5/6/15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 15%</td>
<td>$12.95</td>
</tr>
<tr>
<td>15% and &lt; 25%</td>
<td>$12.95 and $13.50</td>
</tr>
<tr>
<td>25% and &lt; 40%</td>
<td>$13.51 and $14.28</td>
</tr>
<tr>
<td>40% and &lt; 60%</td>
<td>$14.29 and $15.27</td>
</tr>
<tr>
<td>60%</td>
<td>$15.28</td>
</tr>
</tbody>
</table>

provided, however, that if a Change in Control occurs before expiration of the Measurement Period, for purposes of calculating Actual Awards, the TSR will be deemed to have been greater than 60% during the Measurement Period so that the determined Actual Award amount will equal the Maximum Award set forth on APPENDIX B.

(iii) Any Designated Participant who switches from full-time to part-time employment during the Measurement Period will have his or her Actual Award reduced on a pro-rata basis based upon the applicable percentage of full-time equivalent employment that was in effect on an aggregate basis during the Measurement Period. For the avoidance of doubt, no adjustment will be made to the determined amount of an Actual Award for any Designated Participant due to any reduction in the percentage of full-time equivalent employment of a Designated Participant that occurs after expiration of the Measurement Period and prior to expiration of the Performance Period.

(iv) The determined Actual Award amount will become earned by and payable to a Designated Participant subject to (A) attainment of the Performance Period Threshold Goal upon the completion of the Performance Period or the occurrence of a Change in Control prior to the expiration of the Performance Period and (B) the Designated Participant’s satisfaction of the Continuous Service requirements set forth in Section 2(e) below. VWAP will be used on each measurement date to calculate the TSR of the Company’s ordinary shares during the Performance Period in order to determine whether the Performance Period Threshold Goal has been attained. The VWAP on November 5, 2014 was $12.08, so the minimum VWAP on November 4, 2017 that is required for the Performance Period Threshold Goal to be attained is $18.37 (assuming no dividends or distributions are made or declared in respect of the Company’s ordinary shares during the Performance Period). If a Change in Control does not occur prior to expiration of the Performance Period and the VWAP on November 4, 2017 is less than $18.37 so that the Performance Period Threshold Goal is not attained, no Actual Award will be payable under the Program so that the Program will automatically terminate without payment to any Designated Participant.

(e) Continuous Service.

(i) Except as otherwise provided below in Section 2(c)(ii) or 2(c)(iii), in order to earn an Actual Award under the Program, a Designated Participant must remain in Continuous Service through the expiration of the Performance Period. Except as otherwise provided below in Section 2(c)(ii) or 2(c)(iii), if a Designated Participant terminates Continuous Service for any reason prior to the expiration of the Performance Period, the Designated Participant will forfeit the right to any payment under the Program and will not earn an Actual Award.

(ii) If prior to the expiration of the Performance Period, a Designated Participant terminates Continuous Service due to either (A) a termination by the Company without Cause, or (B) the
Designated Participant’s death or Disability and the Designated Participant or his or her beneficiaries (as applicable) provide the Company and its Affiliates with an effective release of claims in a form acceptable to the Company (the “Release”) no later than the earlier of: (i) December 31, 2017, or (ii) fifty five (55) days following a Change in Control that occurs prior to the expiration of the Performance Period, the Designated Participant will still be eligible to earn an Actual Award subject to the Company’s attainment of the Performance Goals during the Performance Period or the earlier occurrence of a Change in Control. If Plan payments are to be made in connection with a Change in Control event and the Release could become effective in more than one taxable year depending on the timing of provision, the Release will not be deemed effective until the latest taxable year in which it could be effective. In no event will Plan payments be made prior to the effectiveness (or deemed effectiveness) of the Release.

(iii) All Designated Participants who remain in Continuous Service through the date of a Change in Control that occurs prior to the expiration of the Performance Period will have earned an Actual Award.

3. Other Program Provisions.

(a) Determination and Payment of Actual Awards. Assessment of actual performance, determination of the Actual Awards and any payment in respect of Actual Awards will be subject to: (i) the Committee’s certification in writing that the applicable Performance Goals and other terms of the Program have been met; provided, however, that such certification requirement shall not be applicable in the event of a Change in Control that occurs prior to expiration of the Performance Period. All Actual Awards which are earned under the Program will be paid to Designated Participants as soon as administratively practicable following expiration of the Performance Period but in no event later than December 31, 2017; provided however that if a Change in Control occurs during the Performance Period, Actual Awards earned under the Program will be paid to Designated Participants as soon as practicable but in no event later than sixty (60) days following the Change in Control.

(b) Withholding. The Company will withhold from payment of any Actual Award an amount in satisfaction of any federal, state or local tax withholding obligation relating to the payment of the Actual Award as necessary to satisfy the Company’s required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income.

(c) No Employment or Service Rights. Nothing in the Program or any instrument executed pursuant to the Program will (i) confer upon any Designated Participant any right to continue to be retained in the employ or service of the Company or any other Affiliate, (ii) change the at-will employment relationship between the Company or any other Affiliate and a Designated Participant, or (iii) interfere with the right of the Company or any other Affiliate to discharge any Designated Participant or other person at any time, with or without Cause, and with or without advance notice.

(d) Program Administration. The Committee will be responsible for all decisions and recommendations regarding Program administration and retains final authority regarding all aspects of Program administration, interpretation of the Program, the resolution of any disputes, and application of the Program in any respect to a Designated Participant. All determinations and interpretations made by the Committee in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons. The Committee may, without notice, amend, suspend or terminate the Program; provided, however, that no such action may adversely affect any Designated Participant unless (i) expressly provided by the Committee; and (ii) with the consent of the Designated Participant, unless such action is necessary to comply with any applicable law, regulation or rule.

(e) Recovery. Any amounts paid under the Program will be subject to recoupment in accordance with any clawback policy that the Company adopts pursuant to the listing standards of any national
securities exchange or association on which the Company’s securities are listed or as is otherwise adopted pursuant to the Dodd-Frank Wall
Street Reform and Consumer Protection Act or other applicable law. No recovery of compensation under such a clawback policy will be an event
giving rise to a right to resign for “good reason” or “constructive termination” (or similar term) under any plan of or agreement with the
Company.

(f) **Validity.** If any provision of the Program is held invalid, void, or unenforceable, the same will not affect, in any respect whatsoever, the
validity of any other provision of the Program.

(g) **Section 409A.** All Program payments are intended to satisfy the requirements for an exemption from application of Section 409A
provided under Treasury Regulations Sections 1.409A-1(b)(4) to the maximum extent such exemption is available. To the extent Program
payments are subject to Section 409A, Program payments are intended to be paid on the earlier of a “specified date” or upon a Change in Control
in compliance with the requirements of Section 409A. Program payments are intended to qualify for an exemption from application of
Section 409A or comply with its requirements to the extent necessary to avoid adverse personal tax consequences to the Designated Participants
under Section 409A, and any ambiguities herein shall be interpreted accordingly.

(h) **Governing Plan Document.** The Program is subject to all the provisions of the Equity Incentive Plan and is further subject to all
interpretations, amendments, rules and regulations that may from time to time be promulgated and adopted by the Committee, the Board or the
Company pursuant to the Equity Incentive Plan. In the event of any conflict between the provisions of this Program and those of the Equity
Incentive Plan, the provisions of the Equity Incentive Plan will control unless necessary for compliance with Section 162(m) of the Code or as
necessary to avoid adverse personal tax consequences to the Designated Participants under Section 409A.
APPENDIX A
CASH LONG TERM INCENTIVE PROGRAM
DEFINITIONS

(a) “Actual Award” means the amount of cash bonus awarded to a Designated Participant under the Program based on the Committee’s determination of the level of achievement of the Performance Goals during the Measurement Period and the Performance Period.

(b) “Cause” for the Company or an Affiliate to terminate a Designated Participant’s employment shall mean the occurrence of any of the following events, as determined reasonably and in good faith by the Committee:

(1) the Designated Participant’s gross negligence or willful failure to substantially perform his duties and responsibilities to the Company or Affiliate or willful and deliberate violation of a Company or Affiliate policy;

(2) the Designated Participant’s conviction of a felony or the Designated Participant’s commission of any act of fraud, embezzlement or dishonesty against the Company or Affiliate or involving moral turpitude that is likely to inflict or has inflicted material injury on the business of the Company or an Affiliate, to be determined by the sole discretion of the Committee;

(3) the Designated Participant’s unauthorized use or disclosure of any proprietary information or trade secrets of the Company or an Affiliate or any other party that the Designated Participant owes an obligation of nondisclosure as a result of the Designated Participant’s relationship with the Company or an Affiliate; and

(4) the Designated Participant’s willful and deliberate breach of any employment obligations that causes material injury to the business of the Company or an Affiliate.

(c) “Certification Date” means the date on which the Committee certifies whether the Performance Goals have been met under the Program. The Certification Date will be no later than December 15, 2017.

(d) “Change in Control” means the first to occur of (1) a change in the ownership of the Company, (2) a change in the effective control of the Company or (3) a change in the ownership of a substantial portion of the Company’s assets as specified below. For such purposes, a change in ownership of the Company occurs on the date on which any one person or more than one person acting as a group acquires ownership of shares of the Company that, together with shares held by such person or group constitutes more than 50% of the total fair market value or total voting power of the shares of the Company. A change in the effective control of the Company occurs on the date on which either (i) a person or more than one person acting as a group acquires during any 12-month period ownership of shares of the Company possessing 50% or more of the total voting power of the shares of the Company or (ii) a majority of members of the Company’s board of directors is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Company’s board of directors prior to the date of the appointment or election. A change in the ownership of a substantial portion of assets occurs on the date on which any one person or more than one person acting as a group acquires assets from the Company that have a total gross fair market value equal to or more than 75% of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions. The determination of whether a Change in Control has occurred will be determined in a manner consistent with the requirements of Section 409A.

(e) “Committee” means the Compensation Committee of the Board of Directors.
(f) “Disability” means the Designated Participant is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than 12 months, or is, by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than 12 months, receiving income replacement benefits for a period of not less than three months under an accident and health plan covering Company employees. The determination of whether a Designated Participant has incurred a Disability will be determined in a manner consistent with the requirements of Section 409A.

(g) “Equity Incentive Plan” means the Horizon Pharma Public Limited Company 2014 Equity Incentive Plan, as may be amended.

(h) “Performance Period Threshold Goal” means the TSR, if any, during the Performance Period which is greater than or equal to 15%.

(i) “Section 409A” means Section 409A of the Internal Revenue Code of 1986, as amended from time to time, including regulations and other guidance thereunder, and any state law of similar effect.

(j) “TSR” means the percentage change in the price of the Company’s ordinary shares on a compounded annualized basis plus the dollar value of dividends and distributions made or declared divided by the closing price of the Company’s ordinary shares on the record date of the dividends and distributions.

(k) “VWAP” means the trailing 20-trading-day volume weighted average price of the Company’s ordinary shares as reported on Nasdaq.
EXCLUSIVE DISTRIBUTION AGREEMENT - AMENDMENT No. 3

THIS AGREEMENT is made the 22 day of September 2014

BY AND BETWEEN:

(1) HORIZON PHARMA AG a company incorporated in accordance with the laws of Switzerland with its registered office at Kägenstrasse 17, CH-4153 Reinach, Switzerland (the “Principal”); and

(2) MUNDIPHARMA INTERNATIONAL CORPORATION LIMITED a company incorporated in accordance with the laws of Bermuda with its registered office at Canon’s Court, 22 Victoria Street, Hamilton, HM 12 Bermuda (the “Distributor”).

RECITALS:

(A) WHEREAS, the Principal and Distributor entered into that certain Exclusive Distribution Agreement dated November 4, 2010, as amended March 5, 2012 and October 25, 2013 (“EDA”), to have the Product registered, marketed, sold and distributed by the Distributor in the Field in the Territory (the terms Product, Field and Territory are defined in the EDA); and

(B) WHEREAS, the PARTIES now wish to further amend the EDA.

NOW THEREFORE, in consideration of the mutual undertakings and covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the PARTIES hereto, intending to be legally bound, agree as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 As used in this Agreement, capitalized words and expressions shall have the meanings defined in the EDA including this AMENDMENT, provided that, in this Agreement, the following words and phrases shall have the following meanings:

“AMENDMENT” means this Agreement between the PARTIES as set out and described herein.

“COMMENCEMENT DATE” means (1) November 4, 2010 with respect to the following countries in the Territory: Australia, China, Hong Kong, Indonesia, Korea, Malaysia, New Zealand, Philippines, Singapore, South Africa, Taiwan, Thailand, and Vietnam; (2) March 5, 2012 with respect to the following countries in the Territory: Mexico, Brazil, Argentina, Colombia, Venezuela, Peru, Chile, Ecuador, Dominican Republic, Guatemala, Costa Rica,
Uruguay, Bolivia, Panama, Nicaragua, El Salvador and Honduras; and (3) October 25, 2013 for: Algeria, Angola, Bahrain, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Congo, Cote D’Ivoire, Democratic Republic of the Congo, Djibouti, Egypt, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Ghana, Guinea, Iran, Iraq, Jordan, Kenya, Kuwait, Lebanon, Lesotho, Libya, Madagascar, Malawi, Mali, Mauritius, Morocco, Mozambique, Namibia, Nigeria, Oman, Qatar, Rwanda, Saudi Arabia, Senegal, Seychelles, Sierra Leone, Somalia, South Sudan, Sudan, Swaziland, Tanzania, Togo, Tunisia, U.A.E, Uganda, Yemen, Zambia, Zimbabwe, Cambodia, Myanmar, Laos, and Brunei.

“PARTIES” means Principal and Distributor collectively.

1.2 Any reference in this AMENDMENT to “writing” or cognate expressions includes a reference to facsimile transmission.

1.3 The headings in this AMENDMENT are for convenience only and shall not affect its interpretation.

1.4 References to “persons” includes individuals, bodies corporate (wherever incorporated), unincorporated associations and partnerships.

1.5 Any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re-enacted.

2. AMENDMENTS TO THE EDA

2.1 Replace Section 2.3.1 of the EDA, in its entirety, with the following:

“For all countries in the Territory with a Commencement Date that is the October 25, 2013, Distributor shall, prior to selling, marketing, distributing or otherwise making available or offering Product for sale in such country, obtain, at its sole cost, the Trademark, or if the Trademark is for any reason not available in such country any other trademark of its choice provided that such Trademark is acceptable to the Principal and provided further that the Trademark will upon Principal’s written request, be transferred to the Principal subject to the Principal’s obligation to reimburse the Distributor for all reasonably incurred direct and indirect costs.”
2.2 Replace Section 5.2.1 of the EDA, in its entirety, with the following:

“The terms described in Section 5.2 will not apply to any of countries in the Territory with a Commencement Date that is October 25, 2013.”

2.3 Schedule 1 of the EDA is hereby amended to add the following additional countries:

“Cambodia, Myanmar, Laos, and Brunei.”

2.4 Schedule 3 of the EDA is hereby amended to add the following Milestone Payment:

<table>
<thead>
<tr>
<th>“Milestone Event”</th>
<th>Milestone Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amount to be paid within five (5) business days of the signature of this AMENDMENT</td>
<td>US$ […]***…</td>
</tr>
</tbody>
</table>

3. GENERAL

3.1 In all other respects, the EDA remains unchanged and in full force and effect.

IN WITNESS WHEREOF, the PARTIES hereto have caused this AMENDMENT to be executed in duplicate by their duly authorized officers as of the date first above written.

HORIZON PHARMA AG

By: /s/ Hans-Peter Zobel
Name: Hans-Peter Zobel
Title: Managing Director Horizon Pharma AG

MUNDIPHARMA INTERNATIONAL CORPORATION LIMITED

By: /s/ Douglas Docherty
Name: Douglas Docherty
Title: Managing Director

HORIZON PHARMA AG

By: /s/ Robert W. Metz
Name: Robert W. Metz
Title: Managing Director Horizon Pharma AG
MANUFACTURING AND SUPPLY AGREEMENT - AMENDMENT No. 3

THIS AGREEMENT is made the 22 day of September 2014

BY AND BETWEEN:

(1) HORIZON PHARMA AG a company incorporated in accordance with the laws of Switzerland with its registered office at Kägenstrasse 17, CH-4153 Reinach, Switzerland ("Horizon"); and

(2) MUNDIPHARMA MEDICAL COMPANY a partnership organized in accordance with the laws of Bermuda with Registered No. EC – 16260 and with its registered office at Canon’s Court, 22 Victoria Street, Hamilton, HM 12 Bermuda ("Mundipharma").

RECITALS

(A) WHEREAS, Horizon and Mundipharma entered into that certain Manufacturing and Supply Agreement dated November 4, 2010, as amended March 5, 2012 and October 25, 2013 (“MSA”), to have Horizon procure the manufacture of the Products and supply the same and have designated Mundipharma to purchase the Products from Horizon for distribution in accordance with that certain Exclusive Distribution Agreement between Horizon and Mundipharma International Corporation Limited dated November 4, 2010, as amended March 5, 2012 and October 25, 2013 (“EDA”); and

(B) WHEREAS, Horizon and Mundipharma now wish to amend the MSA.

NOW THEREFORE, in consideration of the mutual undertakings and covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the PARTIES hereto, intending to be legally bound, agree as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 As used in this Agreement, capitalized words and expressions shall have the meanings defined in the MSA, provided that, in this Agreement, the following words and phrases shall have the following meanings:

- “AMENDMENT” means this Agreement between PARTIES as set out and described herein.
- “PARTIES” means Horizon and Mundipharma collectively.

1.2 Any reference in this AMENDMENT to “writing” or cognate expressions includes a reference to facsimile transmission.
1.3 The headings in this AMENDMENT are for convenience only and shall not affect its interpretation.

1.4 References to “persons” includes individuals, bodies corporate (wherever incorporated), unincorporated associations and partnerships.

1.5 Any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re-enacted.

2. AMENDMENTS TO THE MSA

2.1 Schedule 1 of the MSA is amended to add the following additional countries:

“Cambodia, Myanmar, Laos and Brunei.”

3. GENERAL

3.1 In all other respects, the MSA remains unchanged and in full force and effect.

IN WITNESS WHEREOF, the PARTIES hereto have caused this AMENDMENT to be executed in duplicate by their duly authorized officers as of the date first above written.

HORIZON PHARMA AG

By: /s/ Hans-Peter Zobel
Name: Hans-Peter Zobel
Title: Managing Director Horizon Pharma AG

MUNDIPHARMA MEDICAL COMPANY

By: /s/ Douglas Docherty
Name: Douglas Docherty
Title: Managing Director

HORIZON PHARMA AG

By: /s/ Robert W. Metz
Name: Robert W. Metz
Title: Managing Director Horizon Pharma AG
### Exhibit 21.1

**Subsidiaries of Horizon Pharma Public Limited Company:**

<table>
<thead>
<tr>
<th>NAM:</th>
<th>JURISDICTION OF INCORPORATION:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horizon Pharma Holdings Limited</td>
<td>Ireland</td>
</tr>
<tr>
<td>Horizon Pharma Capital Limited</td>
<td>Ireland</td>
</tr>
<tr>
<td>Horizon Pharma Finance Sarl</td>
<td>Luxembourg</td>
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<tr>
<td>Horizon Pharma Finance Limited</td>
<td>Ireland</td>
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<td>Horizon Pharma Holdings USA, Inc.</td>
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<td>HZNP USA Inc.</td>
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<td>Delaware</td>
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<tr>
<td>Horizon Pharma USA, Inc.</td>
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<td>Switzerland</td>
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<td>Horizon Pharma GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>Horizon Pharma Holdings 2 Limited</td>
<td>Ireland</td>
</tr>
<tr>
<td>Horizon Pharma Services Limited</td>
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<td>Horizon Pharma Tri Limited</td>
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<tr>
<td>Horizon Pharma Ceathair Limited</td>
<td>Ireland</td>
</tr>
</tbody>
</table>
CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333-198852) and S-8 (No. 333-198865) of Horizon Pharma plc of our report dated February 27, 2015 relating to the financial statements, financial statement schedule and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Chicago, Illinois
February 27, 2015
I, Timothy P. Walbert, certify that:

1. I have reviewed this annual report on Form 10-K of Horizon Pharma plc (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: February 27, 2015

/s/ Timothy P. Walbert
Timothy P. Walbert
President, Chief Executive Officer and
Chairman of the Board
(Principal Executive Officer)
Certification

I, Paul W. Hoelscher, certify that:

1. I have reviewed this annual report on Form 10-K of Horizon Pharma plc (the “registrant”);

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: February 27, 2015

/s/ Paul W. Hoelscher
Paul W. Hoelscher
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)
CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and 18 U.S.C. Section 1350, I, Timothy P. Walbert, President, Chief Executive Officer and Chairman of the Board of Horizon Pharma plc (the “Company”), certify to the best of my knowledge that:

1. The Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2014 (the “Report”), to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2015

/s/ Timothy P. Walbert
Timothy P. Walbert
President, Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.
CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and 18 U.S.C. Section 1350, I, Paul W. Hoelscher, Executive Vice President and Chief Financial Officer of Horizon Pharma plc (the “Company”), certify to the best of my knowledge that:

1. The Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2014 (the “Report”), to which this Certification is attached as Exhibit 32.2, fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2015

/s/ Paul W. Hoelscher
Paul W. Hoelscher
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.